

Evaluation of Results Based Financing Strategies for Tuberculosis care and Control in India



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Abbreviations

ACSM	Advocacy, Communication and Social Mobilization
AFB	Acid-Fast Bacilli
AKT	Anti-Koch's Tablet
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activists
ATT	Anti-Tuberculosis Treatment
AYUSH	Ayurveda, Yoga And Naturopathy, Unani, Siddha And Homeopathy
BAMS	Bachelor of Ayurvedic Medicine and Surgery
CME	Continuing Medical Education
CHC	Community Health Center
CT scan	Computed Tomography scan
CTD	Central TB Division
DCH	Diploma in Child Health
DMC	Designated Microscopy Center
DOTS	Directly Observed Treatment Short course
DST	Drug Sensitivity Testing
DTC	District TB Center
DTO	District TB Officer
ESI	Employees State Insurance
ESR	Erythrocyte Sedimentation Rate
GoI	Government of India
GP	General Practitioner
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
ICTC	Integrated Counseling and Testing Center
IGRA	Interferon-Gamma Release Assay
IMA	Indian Medical Association
IPA	Indian Pharmaceutical Association
KG Halli	Kadugondana Halli (Area in Bangalore city, Karnataka, India)
LT	Laboratory Technician
MBBS	Bachelor of Medicine, Bachelor of Surgery
MD	Doctor of Medicine
MDR-TB	Multi-drug resistant TB
MoU	Memorandum of Understanding
MO	Medical Officer
MRI	Magnetic Resonance Imaging
MS	Master of Surgery
NGOs	Non-Governmental Organizations
NSP	New Sputum Positive
NTP	National Tuberculosis Program
OPD	Outpatient Department

PHC	Primary (or Public) Health Center
PPM	Public-Private Mix
PPP	Public Private Partnership
PPs	Private Practitioners
PSP	Private Sector health Provider
RCH	Reproductive and Child Health
RNTCP	Revised National TB Control Program
SC	Sputum Collection
SIDA	Swedish International Development Cooperation Agency
STLS	Senior TB Laboratory Supervisor
STO	State TB Officer
STS	Senior Treatment Supervisor
SVIRHC	Swami Vivekananda Integrated Rural Health Center
TB	Tuberculosis
UHC	Urban Health Center
WHA	World Health Assembly
WHO	World Health Organization

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Executive summary

Recognizing the critical need to engage with Private Practitioners (PPs), the Government of India (GoI) introduced Public-Private Mix (PPM) schemes to involve them in the Revised National TB control Program (RNTCP). Studies have identified a number of barriers for effective collaborations between RNTCP and PPs. Additional research was required to understand the dynamics of the private TB market and PPs' motivations and disincentives to participate in PPM schemes. This study was conducted in two locations in Karnataka state, namely Tumkur district (rural) and KG Halli (urban slum) in Bangalore. Mixed method study design was used. It involved primary and secondary data collection, thematic analysis of qualitative data collected through interviews with PPs, RNTCP staff, technocrats (providing technical assistance to GoI), TB patients who have completed private TB treatment, private diagnostic laboratory technicians, and private pharmacies.

It was found that there was a lack of trust and mutual understanding between the public and private providers. PPs raised concerns about the poor functioning of RNTCP, such as long turnaround time for sputum examination, problems with DOTS delivery, technical incompetence of medical staff in government primary health centers (PHCs) to deal with drug toxicity, bureaucratic hurdles in disbursement of incentives, etc. One important problem was that RNTCP treated all private health providers equally, ignoring the vast diversity of the private health sector. The straitjacket approach of RNTCP was also pointed out by RNTCP officials as a barrier for collaboration. The fundamental problems were the non-alignment of motivations, ideologies, and mode of functioning of the public and private sectors.

Expenditure analysis for TB care showed that a TB patient spends up to INR 21,000.00 (~USD 350) on direct health care cost. A small chunk of this expenditure went towards doctors' consultation fees. PPs have a significant financial incentive to retain TB patients since they also receive kickbacks from diagnostic laboratories and pharmacies (~30%), in addition to consultation fees. Thus, PPs can earn up to INR 8000 (~USD 140) from treating a single TB patient. This makes any financial incentive offered by the government under PPM schemes seem insignificant to PPs, especially when coupled with the bureaucratic hassles of obtaining that amount. Kickbacks seem to be entrenched in the private health care setup with some large establishments even maintaining systematic ledgers for this purpose. It was observed that kickbacks became less common in areas where the public sector health facilities were reputed. Thus, the bargaining power of PPs is inversely proportional to the strength of the public health system in an area. Assessment of the regulatory environment to engage with PPs demonstrated that PPs were largely aware about TB notification, but less aware of the exact mechanism and procedures.

It is recommended that the RNTCP re-examine the mechanisms of collaborating with the PPs and become more flexible to accommodate the diverse private health sector.

The current model of results-based financing needs a rethink to include creative non-financial measures and decentralized and non-bureaucratic administration of locally appropriate incentives. PPM activities should also be closely monitored with improved reporting systems. TB control regulations should be widely advertised and then strictly enforced.

Chapter 1

Introduction

1.1. Evolution of Revised National TB Control Program

The World Health Assembly (WHA) declared Tuberculosis (TB) to be a ‘Global emergency’ and adopted the DOTS (Directly Observed Treatment Short course) strategy for control of TB in 1993 (1). TB remains a major health problem in India and accounts for 26% of all TB cases worldwide, with an estimated annual incidence of 176 cases per 100,000 persons in 2012 (2), (3). In 2006, TB resulted in an estimated USD 23.7 billion loss to Indian exchequer (World Health Organization, 2010).

The National Tuberculosis Program (NTP) in India has been in existence since 1962. However, treatment success rates were unacceptably low and death and default rates remained high. Further, the HIV/AIDS epidemic and the spread of multi-drug resistant TB (MDR-TB) further worsened the situation. In view of this, the GoI along with international agencies such as WHO and SIDA, reviewed the TB situation in 1992 and concluded that the NTP, though technically sound, suffered from certain gaps, such as managerial weaknesses, inadequate funding, over-reliance on X-rays for diagnosis, interrupted drugs supply, and low rates of treatment completion. In order to overcome these gaps, the GoI in 1993, with assistance from international agencies, decided to give a new thrust to TB control activities by revitalizing the NTP. The RNTCP was thus formulated with the following

Objectives: (1) to achieve and maintain case detection of at least 70% of the estimated New Sputum Positive (NSP) cases in the community and (2) to achieve and maintain a cure rate of at least 85% among NSP patients (5). The program was launched in several phases.

Pilot Phase (1993–1995): Pilot programs were conducted between 1993 and 1995 to test the operational feasibility. The RNTCP adopted the internationally recommended DOTS strategy comprising the following five components: (1) Political and administrative commitment; (2) Good quality diagnosis, primarily by sputum smear microscopy; (3) Uninterrupted supply of quality drugs; (4) Directly observed treatment (DOT); and (5) Systematic monitoring and accountability.

Phase I (1997-2006): During this phase, the RNTCP focused on high quality DOTS expansion in the country addressing the five primary components of the DOTS strategy. By March 2006, the entire country was covered by RNTCP (World Health Organization, 2010).

Phase II (2006-2011): In 2006, WHO announced the ‘STOP TB Strategy’. This was adopted by the RNTCP and all activities proposed under the strategy were covered,

such as pursuing quality DOTS expansion, addressing TB/HIV and MDR-TB, promoting health system strengthening, involving all care providers, empowering patients and communities, enabling and promoting research (7).

Phase III (2012–2017): In Phase III, the RNTCP seek to achieve universal access to quality TB diagnosis and treatment. The GoI prepared the National Strategic Plan (2012-2017) with the vision to move towards universal access for quality diagnosis and treatment for all TB patients in the community (8).

There has been a marked growth of the private health sector in India over the years. Most patients with respiratory symptoms first consult Private Sector health Providers (PSPs) (9)-(15) . There are several published studies, which reveal that TB patients first seek the help of PSPs and that on average there is a delay of about two to three months between the onset of the symptoms and the diagnosis of TB. In the private sector, TB is often inaccurately diagnosed (16) and ineffectively treated, with poor treatment outcomes. Several researchers have documented damaging practices of PSPs, such as unnecessary investigations and inappropriate drug prescriptions.

PSPs do not adhere to national or international TB standards of care which often leads to avoidable treatment delays, relapses, and acquired drug resistance due to poor prescribing practices (17)-(24).

1.2. Efforts by RNTCP to engage private sector health providers

Recognizing the critical need to engage with PSPs in TB control, the GoI made efforts to involve them in the RNTCP through the PPM-DOTS strategy. Efforts were made to link the RNTCP with all public and private health care providers to detect TB symptoms at an early stage and provide standardized treatment to TB patients based on the guidance from WHO (25). The Indian health system is complex and involves a wide range of health care providers ranging from unqualified practitioners to highly trained specialists. See Table 1 for a typology of health care providers in India. Medical colleges treat a significant number of TB cases in the country. They also play an important role in health service delivery, advocacy, training, and operational research of TB related activities.

Recognizing their significance, the GoI, in 1997, conducted a national consensus conference on TB to involve medical colleges in the RNTCP. Efforts were made to create core committees in each medical college to overview RNTCP activities (26), (27).

During 2000-2003, PPM-DOTS models were piloted in Delhi, Kannur, Kollam, Mumbai, and tea garden hospitals in North East India with encouraging results (28), (29), (30), (31), (32). Using the experiences gained from these collaborations with PSPs, the GoI published formal PPM guidelines to help local program officers structure collaborations with Non-Governmental Organizations (NGOs) and PPs, in 2000 and 2001, respectively (33), (34). Depending on the capacity of the partners,

they could get involved in a diverse set of plans for the community of private providers, with options to participate in the referral, diagnosis, or treatment of patients with tuberculosis.

Table 1: Typology of health care providers in India		
Type of Providers	Formal providers	Informal providers
For-Profit	<ul style="list-style-type: none"> • Qualified providers having clinics, polyclinics, nursing homes, and corporate hospitals • Medical colleges 	<ul style="list-style-type: none"> • Unqualified providers (Quacks) • Retail Pharmacists • Providers trained in alternate medicine, but practicing allopathic medicine
Not-For-Profit	<ul style="list-style-type: none"> • Government hospitals • Public sector hospitals (e.g., Port, Mining, and prison hospitals) • Faith-based hospitals • Charitable hospitals 	<ul style="list-style-type: none"> • Voluntary village health workers

Later, a need was felt to involve PSPs, particularly in the urban areas, due to their diversity and large numbers. This resulted in the launching of the ‘Intensified PPM project’ in 14 urban areas in the country by the GoI in August 2003. This project was set up to systematically undertake intensified PPM activities and to document the contribution of different health providers towards case detection and treatment under RNTCP in urban areas (26), (35). In India, there are a large number of health facilities under the public sector, such as railways, steel, ports, coal, and mines which are outside the purview of the Health Ministry. They have their own health facilities catering to millions of people who receive subsidized or free services from these facilities. Using the PPM approach, the RNTCP has made efforts to involve these public sector health facilities in the program (36), (37).

However, the efforts of RNTCP have not borne fruit in incorporating the PPM schemes under the formal agreement. A need was felt for the revision of existing schemes in the light of newer initiatives, such as DOTS plus and TB-HIV collaboration, to improve the access of DOTS. Therefore, the GoI after wide consultations with academicians and civil society members revised the NGO/PP schemes of 2000-2001, and the revised PPM guidelines came into effect from October 2008 (38). There are currently ten PPM schemes. Eligible PSPs can choose to participate in any of these schemes depending on their infrastructure and managerial capacity. Each scheme has specific aims that the partnership must fulfill, and eligibility requirements for both participation of potential partners in the scheme and available incentives. Box 1

Box 1: Public Private Mix schemes in RNTCP

Scheme for Advocacy, Communication and Social Mobilization (ACSM): This scheme expects NGOs to mobilize local political commitment and resources for TB, empower communities affected by TB, and reduce the stigma and discrimination against persons affected by TB. A total grant-in-aid of INR 150,000/- per one million population per year will be provided.

Scheme for Sputum Collection (SC) center: Any institution working in 'under-served' areas, complying with the strict quality assurance requirements can participate in this scheme to collect sputum samples. An incentive of INR 60,000/- per annum per SC center will be provided.

Scheme for Sputum Pick up and Transport Service: Any NGO with outreach activities can engage in the scheme to transport sputum sample to the nearest DMCs (Designated Microscopy Centers), for sputum microscopy. Grant-in-aid of INR 24,000 per annum for a maximum of 20 visits per month will be provided.

Scheme for DMC and treatment center: In this scheme, NGOs/private laboratories can engage to provide sputum microscopy and TB treatment services free of charge. The annual grant-in-aid is INR 150,000.

Laboratory Technician (LT) Scheme: This scheme aims at strengthening the RNTCP diagnostic services and ensuring that there are human resources available to operate DMCs in the public sector hospitals. The grant-in-aid will be as per the existing RNTCP contractual laboratory technician salary plus 5% overhead. Recruitment cost reimbursement equivalent to one month salary will also be provided.

Culture and DST (Drug Sensitivity Testing) Scheme: Existing well-functioning mycobacterial culture and DST laboratories in the private/NGO sector can apply under this scheme. The fee payable for sputum / smear culture, species identification, and DST for first line anti-TB drugs will be INR 2000 per specimen.

Adherence Scheme: This scheme proposes to engage NGOs and PSPs to ensure patient compliance to their drug regimen. For NGOs, INR 40,000 for every 100,000 population per annum, pro-rated for population served will be provided. For PSPs, INR 400/- per patient successfully treated will be provided.

Slum Scheme: This scheme aims to address the problems of urban slum dwellers that require additional support. PSPs and self-help groups can engage in the scheme to ensure patients compliance to drug regimens and timely diagnosis. An incentive of INR 50,000 per 20,000 population per annum will be provided.

Tuberculosis Unit Model: This is primarily designed for areas where there is an already existing and effective NGO currently working in the field that can carry out all the RNTCP services typically executed by RNTCP TB units. An annual grant-in-aid of INR 53,000 will be provided.

TB-HIV Scheme: This scheme is primarily designed to address the needs of TB-HIV co-infected patients. NGOs already working with HIV patients can engage in this scheme to help treat TB under DOTS in conjunction with their HIV treatment. The grant-in-aid for the scheme is a consolidated INR 120,000/annum for a target population of 1000.

The GoI has been also making efforts to involve private pharmacies in the program because they play an important role in TB care in India. After successful pilots in 2006, the RNTCP has engaged with the Indian Pharmaceutical Association (IPA), wherein private pharmacists are trained to detect chest symptomatic cases and refer them to nearby DMCs for TB diagnosis. Later in 2011-2012, efforts were made to involve civil society in TB diagnosis, such as faith-based organizations, community-based non-profit NGOs, patient-based organizations, and professional associations such as the Indian Medical Association (IMA). A forum named the ‘Civil Society Partnership for Tuberculosis Control and Care in India’ was formed to bring together civil society across the country on a common platform to support and strengthen India’s TB control efforts. On the same lines, another initiative Project Axshya (meaning TB-free) was implemented by the Union in 374 Districts across 23 States with the objective of improving access to quality TB care and control through a partnership between government and civil society. Table 2 depicts the evolution of PPM-DOTS in India.

Table 2: Evolution of PPM DOTS in India	
Year	Milestones
1993	RNTCP started in pilot districts
1997	National consensus conference to involve medical colleges
2000-2003	PPM-DOTS models in Delhi, Kannur, Kollam, Mumbai, tea garden hospitals in North East India North East India
2001-2002	PPM-DOTS Schemes for involvement of PSPs published
2002-2003	PPM activities started in all the states
2003	Intensified PPM scaling up begins in 12 urban sites
2003-2004	Initiatives to involve other government departments, public sector Undertakings
2004	Declaration by the National Indian Medical Council to support RNTCP
2005	Expansion of intensified PPM
2008	Revised PPM schemes rolled out

1.3. Procedures for Administration and Implementation of PPM Guidelines

PPM strategy is based on the principle of results-based financing. According to the RNTCP guidelines, PSPs can choose any PPM scheme depending on their technical, managerial, and infrastructure capability by signing a Memorandum of Understanding (MoU) with the government at different levels for different schemes. The District TB Officer (DTO) is overall in-charge of implementing the program in the district. It is expected that the DTO will line-list all potential PSPs in the district with an estimate of the number of TB patients catered by them and foster coordination at the local

level, and conduct periodic review meetings with PSPs. At the state level, the State TB Officer (STO) provides oversight of the program and allocates required resources to districts to implement the program. The STO is required to provide feedback to the Central TB Division (CTD) located at New Delhi, which is the policy-making body. DTOs can establish collaboration with NGOs for activities under the ACSM scheme without consultation with a higher authority for the approval of the scheme. However, for the DMC, LT, Slum and TB-HIV Schemes, approval has to be obtained from the State TB Cell. For the Culture-DST and Tuberculosis Unit Schemes, the CTD provides approval after obtaining recommendation from both the DTO and the State TB Cell. Figure 1 illustrates the generic PPM model in India.

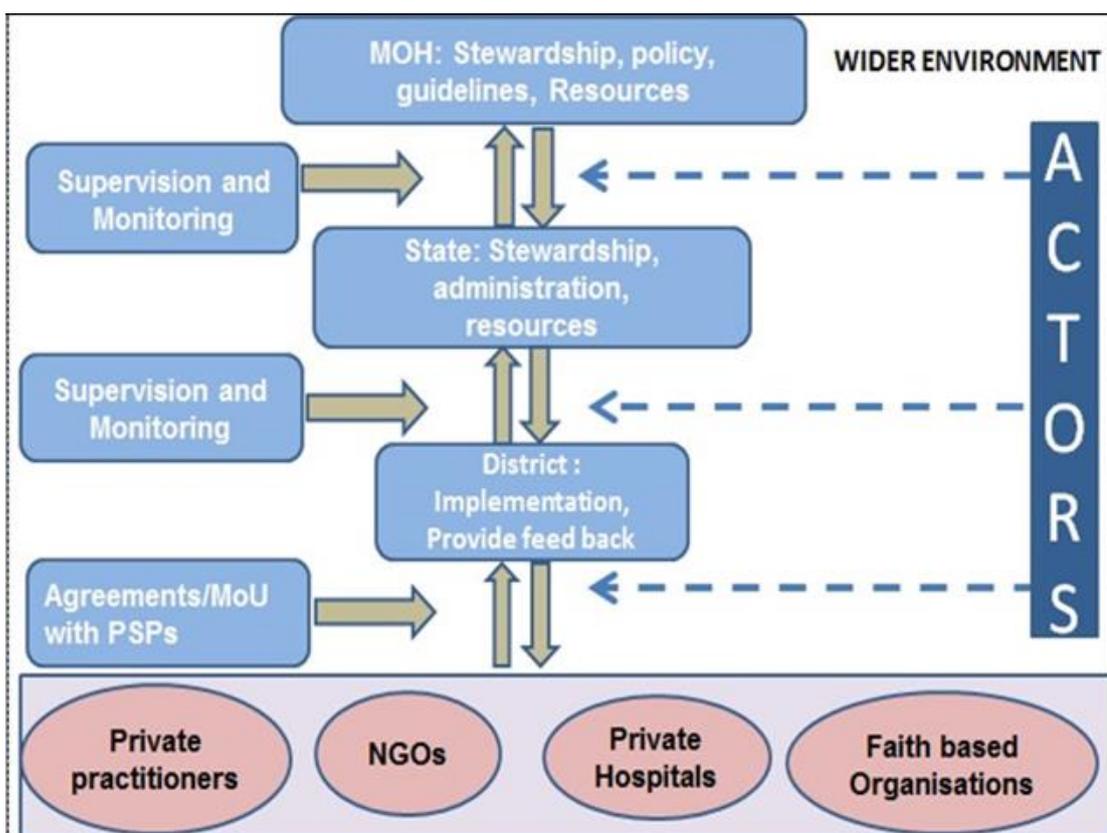


Figure 1: Generic PPM model in India

Source: Adapted from WHO-PPM tool kit

1.4. Assessment of PPM-DOTS Schemes

Several studies have been conducted to assess the feasibility and challenges of the PPM implementation in India. Reports published on the performance of PPM projects indicate that the approach is feasible and effective (29,32,39,40) Dewan et al. (2006) reviewed 14 out of 24 PPM projects. Out of these, data on case notification rates before and after PPM were available, with results indicating that PPM had a positive impact on case notification (41). Another study by Rangan et al. (2003) was conducted in Pune, Maharashtra, to observe the PPM model within the local TB unit.

The study objectives were to create a ‘model’ partnership between private medical practitioners and the RNTCP. The study was implemented and facilitated by a local NGO in the area and was based on participatory research methods. The partnership contributed to 30% of case detection over the 5-month study period. Monitoring of cases even after the end of the study indicated that case referrals continued between PPs and the RNTCP, though to a lesser degree. There were, however, issues with the communication and documentation systems after the official end of the partnership. The study concluded that although the presence of the NGO was critical, it prevented the RNTCP and PSPs from taking the initiative and responsibility to continue the program in the absence of the NGO (42).

A number of studies on cost effectiveness have also been conducted to assess the impact of public-private collaborations for TB control in various states across India. Studies have found that the PPM-DOTS approach for TB control is a cost-effective intervention to increase case-detection rates and treatment outcomes when compared to no collaboration between the public and private sectors for TB care. Floyd et al. (2006) performed a cost-effectiveness analysis on the PPM-DOTS strategy for TB control in the Hyderabad and Delhi PPM projects. The study compared three scenarios: PPM-DOTS, public sector DOTS only, and non-DOTS treatment in the private sector. It was found that public sector costs were lower in the PPM-DOTS programs due to the considerable presence of private providers. The incremental cost ratio per patient successfully treated with PPM-DOTS in Delhi indicated reduced cost and increased effectiveness, from the societal perspective. PPM-DOTS in Hyderabad did not lead to increased costs but did improve effectiveness when compared to non-DOTS treatment in the private sector. Based on the analysis, the researchers were able to conclude that PPM-DOTS can be an effective strategy if there is a strong existing public sector program with visible success (31). Another study by Pantoja and his co-workers in Bangalore city from 1999 to 2005 also established that PPM is cost-effective. Three scenarios were considered for comparison: the actual situation in Bangalore in practice, RNTCP implementation from 1999 to mid-2001 (including only PPM Phase I), and situation of no PPM implementation. Scenario 1 was compared with Scenario 3 to evaluate the effectiveness of RNTCP Phase II, and Scenarios 1 and 3 were compared to evaluate the effectiveness of PPM as a program. When PPM was implemented, the average cost, from the provider perspective per patient treated was at USD 69 in the intensive PPM phase as compared to USD 71 in the pre-PPM phase. PPM led 7200 patients from non-DOTs to DOTS treatment in five years and substantially reduced costs to patients where the average societal cost per patient fell from USD 154 to USD 132 in the four years of PPM implementation. The findings therefore suggest that PPM can be cost-effective for providers and patients in urban areas when compared to no PPM (30).

1.5. Policy Environment

The GoI has made TB a notifiable disease from May 2012, thus making it mandatory for all private sector laboratories,allopathichospitals/clinics/nursing homes and

individual allopathic PPs to report the TB cases diagnosed and/or treated by them to the government authorities (43). PPs can notify the government authorities either by hardcopy (by post, by courier, or by hand), email, mobile phone call, or by SMS, or it may be uploaded directly on to the NIKSHAY portal (explained in the next paragraph). Notification provides an opportunity for the RNTCP to extend the mechanisms of TB treatment adherence to patients treated by private health care providers through counseling of TB patients to promote treatment adherence, follow up to ensure treatment completion, offering chemoprophylaxis as required, offering TB treatment under RNTCP if desired by the patient, etc. It is imperative that, for effective implementation of notification, the DTO performs the mapping of private health establishments.

Another initiative by GoI was the launch of NIKSHAY, a web-enabled application, in June 2012, with the objective to create a database of all TB cases across the country and to then use this database for monitoring and research purposes(3)(43). It is expected that the nodal persons at district TB centers (DTC) will enter all cases notified by private health establishments in NIKSHAY. As a prerequisite, all private health establishments should be registered in NIKSHAY for TB notification by submitting a registration form mentioning the details of the establishment. Health establishments can obtain the registration form either from DTCs or by downloading from <http://tbcindia.nic.in>. Alternatively, health establishments can be automatically registered by the DTC after submission of their first TB notification report. Each health establishment on request for registration for TB notification or submission of first TB notification report will receive a unique number for further correspondence after verification of the submitted details.

Another effort by the GoI was to ban serological tests for the diagnosis of pulmonary or extra-pulmonary TB, as commercially available serological TB tests provided imprecise or inconsistent estimates leading to incorrect diagnoses(44).

1.6. Private Practitioner's Perspectives on Collaboration and Incentives

The concept of PPM has gained much prominence in the health care sector in India. However, there are a number of barriers that exist within the RNTCP, PSPs, and the community that hinder effective and efficient collaborations among them. Though promising, PPM-DOTS strategies have not been pursued and scaled up. Currently, the RNTCP claims that several thousands of PSPs are collaborating under various PPM schemes. However, in reality, the RNTCP Annual Status Report for 2014 reported that only 13,150 formal PPs in the entire country were involved with the RNTCP (3). Given this background, it becomes imperative to understand the perspective of PSPs towards collaboration and the community awareness towards DOTS. Despite critiques that the treatment offered in the private health sector is unsound, sub-standard, and inconsistent, 50-70% of the TB patients in India continue to prefer private health care(45), (46),(10). Vyas et al. (2003) conducted a cross-sectional survey of private

and public physicians to understand the perceptions held by each sector. Significant conflicts in perception were found regarding the interpretation of general facts, attitudes towards each sector, and the effectiveness of DOTS. The authors concluded that such differences in the perception were likely to result in mistrust, conflicting views on reform propositions, contrasting mindsets about social agendas, and reluctance to cooperate (47). Another study by Arora et al. (2003) found that most of the PPs felt that there was no benefit in participating in the RNTCP as far as their own practice and profit were concerned. However, they agreed that their contribution was certainly beneficial for TB control in the community, and 89% of them wanted to continue their association and participation in the project (39). Uplekar et al. (2001) outlined the challenges and perceptions of the private and public sector. Within national TB programs, there may be ideological opposition to engage with the private sector for TB care as well as unwillingness to expend resources in a sector that is an unfamiliar territory for national programs. There may also be resistance to engage with the private sector due to lack of regulation, unorganized presence, and faulty practices by PPs. Within the private medical sector, incentives to engage with the public sector are often missing largely due to the lack of remuneration. There are also administrative barriers in providing the records of patients seen under collaborative efforts as well as distrust of public programs and their program staff. Hence, examining private provider perspectives, incentives, and disincentives for engagement with the public sector for TB care is necessary (45). Several other studies which investigated the challenges of collaboration both from private providers and public sector perspectives revealed that providers cite delays in payment and lack of adequate incentives as reasons for not participating in PPM (48). Anecdotal evidence also suggests that lack of political will at the district level of RNTCP leadership coupled with reluctance from the private sector to collaborate for the fear of losing patients have been impediments to PPM (49). De Costa et al's (2008) study showed that the program staff at the peripheral level exhibited both a lack of interest and experience in dealing with the private sector and had lack of faith in their own capacity. Similarly, private sector also distrust the the public health programs and hence has low priority for such programs (50). All the studies cited above, called for additional research surrounding health care provider motivations and disincentives to participate in PPM schemes and the means through which providers could be encouraged to participate in RNTCP treatment collaboration efforts. While there have been some studies documenting PPM collaboration and the challenges, additional research is needed to understand private sector incentives and methods to increase participation and adherence to the national and international standards for TB care. One of the WHO documents on PPM-DOTS emphasizes the lack of evidence, precedents, and replicable success stories on effective collaboration. The global assessment discovered some interesting working approaches, but not all of them are documented adequately to understand the processes and outcomes. Therefore, this study has been undertaken to document local PPM 'learning projects' (51).

1.7. Study Objectives

The vision of the GoI is to have a ‘TB-free India’. To achieve this, a new strategy has been adopted in RNTCP Phase III (2012–2017) of ‘universal access for quality diagnosis and treatment for all TB patients by engaging all health care providers’ (52), (8). To achieve this objective, RNTCP will need to improve and expand its engagement with private sector providers. Given the challenges of involving PSPs in PPM strategies, This study was conducted with objective of understanding the barriers that existed from the private and public sectors for public-private engagement for TB control, the means to incentivize PSPs to collaborate with RNTCP, and to improve their TB care practices as well. In this study, the researchers focused in particular on for-profit formal PPs. The specific objectives of this study are

- To examine the level and extent of involvement of PPs in PPM-TB schemes.
- To analyze the contribution of PPs to the RNTCP in terms of case detection and treatment outcomes.
- To chart the perceptions of different stakeholders (e.g., PPs, government officials implementing RNTCP, RNTCP field staff, and technocrats) with regard to collaborating with the RNTCP and their preferred modes of collaboration vis-à-vis the expectations of RNTCP program managers’.
- To understand the incentive structure and functioning of the private market for TB services.

Chapter 2

Materials and Methods

2.1. Study Setting

This study was carried out in two sites in the state of Karnataka, India: one, a rural district (Tumkur district) and the other, an urban slum (KG halli) in Bangalore. Figure 2 displays the location of the study sites.

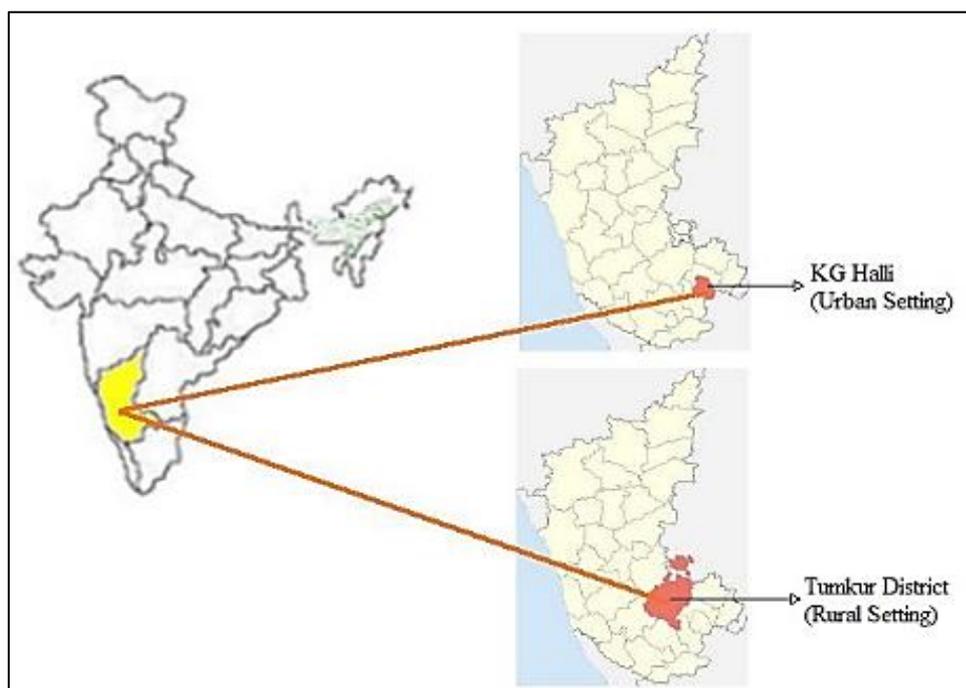


Figure 2: Location of the study sites

Rural setting: Tumkur district is situated 70 km northwest of Bangalore, the capital of Karnataka. It had a population of 2,678,980 in 2011 and is spread over 10,597 km², with a population density of about 253 persons per km². Tumkur district is divided into ten talukas. For the purpose of study, Tumkur district, with the exception of Tumkur city, was considered to be rural, as it is predominantly rural in nature with 80% of the population living in villages. Tumkur district has pluralistic health services with private and public health facilities, and formal and informal providers.

Urban setting: Tumkur city and KG Halli, one of the 198 administrative wards of Bangalore city, were considered to be urban areas. KG Halli has a population of more than 44,000 individuals spread over 0.7 square kilometers. It includes an area classified as a ‘slum’, which is a compact settlement of poorly built tenements with inadequate sanitary and drinking water facilities. There is a government urban health center (UHC) and a first referral Community Health Center (CHC) in this area. There are additionally 32 private health care providers (excluding dentists and paramedics) from various systems of medicine including Unani, Ayurveda, Allopathy, and

Homeopathy. These private health facilities include four hospitals and several single doctor clinics. All the private facilities provide outpatient care. The hospitals also provide inpatient facilities and their capacity ranges from 50 to 100 beds. Table 3 provides the list of TB Units and DMCs in Tumkur district.

Table 3: List of TB Units and DMCs in Tumkur district	
Name of TB Unit	Name of DMCs Under Each TB Unit
Tumkur	District TB Centre, District Hospital Laboratory, Siddhartha medical college
Sira	Kallambella, Panjiganahalli, CN (Chikkanayakana) halli, Huliya, Sira general hospital
Pavagada	Swami Vivekananda Integrated Rural Health Center (SVIRHC), Pavagada general hospital, Madhugiri, Hosakere
Kunigal	Kunigal, Hulyurdurga, Gubbi, C. S.(ChandraShekara) Pura, Chelur
Tiptur	Tiptur, Nonavinakere, Matthighatta, Turuvekere,
Koratagere	Koratagere, Tovinakere, Urdigere, Badavanahalli,

2.2. Study Design

The study was conducted in two phases: Phase One employed a quantitative approach to assess the extent and nature of PP participation in the RNTCP and Phase Two employed a qualitative approach.

Four main methodological tools were employed in the research process. These were; (a) document analysis of relevant published literature, (b) content analysis of regulations and related policy guidelines, (c) field work consisting of secondary data collection from professional associations and RNTCP registers and reports, and primary data collection through in-depth interviews and semi-structured interviews, and (d) document analysis of grey literature.

2.2.1. Quantitative methods – Phase 1

The main objective of Phase One of the study was to assess the participation of PPs in the RNTCP during 2011 from Tumkur district. For this purpose, the focus was on for-profit PPs, formal and informal providers working in clinics, polyclinics, nursing homes, and hospitals, in particular. To allow focus on PPs, collaborations with medical colleges, government health facilities outside the authority of the Indian Ministry of Health, and NGOs were excluded.

The following steps were carried out as part of PhaseOne of the research:

As a first step, RNTCP reports and registers maintained at the DTC were reviewed to assess the involvement of PPs in various PPM schemes for the year 2011. As a second

step, all DMCs in the district were visited between February and April 2013, to assess the actual number of PPs referring TB suspects to DMCs. 'PP referred TB suspect' was defined as a TB suspect referred by a PP, who has undergone sputum examination at a DMC and has been registered in the laboratory register maintained at DMCs. All other suspects were defined as 'public sector referred suspects'. Data was collected retrospectively from the laboratory registers maintained at the DMCs. The names of the individual PPs who had referred TB suspects and their volume of TB suspect referrals during the year 2011 were documented and systematically entered in the database. During the data collection, it was observed that only a few of the DMCs systematically recorded the source of referrals in the lab registers. Hence, for the quantitative data analysis, 5 DMCs out of 28 were selected, in which reliable documentation of source of referrals was available. In the third step, referring PPs were identified by visiting their health facilities. These were then stratified according to the following categories:

- Urban and Rural: Areas administered by city municipal corporations were considered to be urban, areas administered by town unicipal councils were considered to be semi-urban, and areas administered by town and village panchayats were considered to be rural.⁴⁷
- System of Medicine: PPs were broadly categorized as Allopathic: Bachelor of allopathic medicine; AYUSH: Bachelor of Indian system of medicine; None: No training whatsoever (Informal providers).
- Type of Speciality: This categorization was applied to PPs practicing Allopathy. PPs were categorized as General practitioners (GPs), if they had completed their graduation without any further advanced training, or as specialists, if they had pursued any advanced training.
- Type of facility: PPs were classified depending on the level of the care provided: (a) First level of care - clinics having one doctor and polyclinics having more than one doctor, providing OPD care, (b) Second level of care consisting of nursing homes and hospitals, and (c) Tertiary level of care: Corporate hospitals.

As a fourth step, the formal providers in the study area were mapped. As no registry corresponding to the number of PPs practicing in the study area was available, five data sources were used for the mapping: IMA, Karnataka Private Medical Establishment Act, District TB office, private nursing homes list, and medical college faculty list. These sources were complemented by onsite verification.

As a fifth step, the contribution of PPs to the RNTCP was measured by calculating the following indicators:

- Proportion of PPs engaged with RNTCP (number of PPs who are participating in PPM schemes / total number of identified PPs).
- Proportion of TB suspects referred by PPs (number of TB suspects referred by PP / total TB suspects reporting to DMCs).

- Proportion of sputum positive confirmed TB cases detected from those referred for diagnosis by PPs (number of positive cases from those referred for diagnosis by PPs / all positive cases detected).

This quantitative data was analyzed to complement the data collected using qualitative methods.

2.2.2. Qualitative data collection and instruments – Phase Two

Given the complexity of implementing the PPM schemes, a need to gain better understanding of the private TB market dynamics was seen. For this purpose, comprehensive interviews were conducted with PPs, government officials involved with RNTCP implementation and administration, and technocrats providing technical assistance to the government. Semi-structured interviews were conducted with private laboratories performing TB diagnostic tests, private pharmacies dispensing anti-TB drugs, and TB patients who had completed private TB treatment from a PP. The data collection was carried out from May to October 2013. Interview guides were pilot-tested and then modified accordingly. Interviews were preceded by warm up visits to the interviewees in order to elicit quality data. During these visits, information brochures were shared and efforts were made to build rapport. The average duration of the interviews ranged between half-hour to one and a half hours. Table 4 provides an overview of the total number of interviews conducted.

Category of respondents	Total number of interviews
Private practitioners	38
Government officials	4
Technocrats	4
TB patients	28
Private laboratories	40
Private Pharmacies	40
Total interviews	154

The chronology of the interviews was from the bottom up. PPs were first interviewed to identify the issues affecting the collaboration. These issues were then taken to the implementers, administrators, and technocrats. Tools were modified according to the issues, factors, ideas identified at each level (PPs, patients, laboratories, pharmacies, implementers, administrators, and technocrats). This iterative process of data collection helped in constantly validating the findings between different sets of interviews. The sampling of respondents was through purposive sampling, which is explained in the subsequent sub-sections.

Private Practitioners: The quantitative data analysis of RNTCP registers and reports provided the actual number of PPs and the volume of TB suspects referred to DMCs in the year 2011. A total of 881 PPs had referred 936 TB suspects to DMCs in the

year 2011. These PPs were broadly categorized into three categories depending on the volume of their TB suspects referrals as (a) Actively involved: PPs who refer more than 12 TB suspects per year to DMCs, (b) Minimally involved: those PPs who refer more than one and less than 12, and (c) Not (or non) involved: PPs who do not refer TB suspects to DMCs at all.

Actively involved PPs (n=16) were considered for the in-depth interviews. However, interviews could be conducted with only 14 of them (two PPs were out of town during the study period). Through these interviews, the researchers aimed at understanding their motivation to collaborate with the RNTCP, TB suspects' referral patterns, TB management practices, and also to elicit their experience of collaborating with the RNTCP. Similarly, in-depth interviews were conducted with 10 non-involved PPs to understand their TB management practices, their perceptions about collaborating with RNTCP, and the financial incentives received by them while treating TB patients. They were matched with the actively involved category of PPs for age, years of experience, level of care provided, speciality, and location (urban or rural). The opinion of RNTCP staff was sought prior to interviewing minimally involved PPs. Nine such PPs who have more than 50 outpatients / day, but refer these minimally to the DMC, were selected from the list. Seven informal providers having more than 50 outpatients / day were also interviewed. This list of respondents was shared with the DTO and the concerned TB staff at the sub-district level before conducting the interviews, to seek their opinion about the categorization.

Government officials and technocrats: In-depth interviews were conducted with the RNTCP government officials involved in the implementation and administration at sub-district (n=1), district (n=1), and national levels (n=2). In-depth interviews were also conducted with technocrats (n=4).

TB patients: Semi-structured interviews were carried out with TB patients (n=28) to understand the costs incurred towards TB diagnosis, treatment, and other related indirect costs. Seven patients were selected from the urban area and the remaining (n=21) from the rural area. Patients were identified from the clinics of the providers who had participated in the study, and interviewed after obtaining the permission of the providers. Minors under the age of eighteen were excluded.

Private laboratories: Semi-structured interviews were conducted with 40 laboratories (21 from the urban and 19 from the rural areas) to understand their TB diagnostic practices, costs of TB diagnostic tests, and their association with referring PPs, in terms of any kickbacks given to them. Laboratories which performed TB diagnosis routinely were selected on purpose. These laboratories were identified through interviews with PPs and TB patients.

Private Pharmacies: In India, most PPs prescribe drugs, and patients are required to purchase them from private pharmacies. Semi-structured interviews were conducted with 40 private pharmacies (19 urban and 21 rural) in order to understand their

dispensing and procurement practices with regard to TB drugs, and the kickbacks, if any, given to referring PPs. These pharmacies were randomly selected from the list of registered pharmacists maintained with the district drug controller.

2.3. Data Collection and Analysis

Quantitative data analysis was performed using Microsoft Excel. Interviews were transcribed verbatim. Five professional transcribers were hired to transcribe the interview material from the audio-recorded version. Each transcript was then cross-checked by the principal investigator, who is the first author of the report, for missing content and non-verbal gestures. Data were organized based on the category of respondents. Coding was performed based on the main and sub-research questions. Key themes that emerged from each interview were short-listed. To conduct a holistic and comprehensive analysis, data of each category and sub-categories of respondents were analyzed. At each level, data were duly triangulated with other sources (key findings from other interviews, literature, and program guidelines).

2.4. Ethical Issues

The study proposal received approval from the technical committee and the Institutional Ethics Committee of the Institute of Public Health. After line-listing the potential respondents, an appointment was made with the respondents and they were briefed about the study. Respondents were provided with an information brochure about the study (both in English and Kannada). Informed oral consent was chosen due to the apprehensions with regard to signing documents. All interviews were audio recorded, except for one respondent each from the government officials' category, the technocrat category, the private laboratories, and six from pharmacies. Interview venues varied depending on the preferences of the different categories of respondents. There were some refusals among patients, laboratories and pharmacies to participate in the study. Table 5 shows the number of refusals and the reasons for the same. The recordings were kept anonymous to maintain confidentiality during the process of data transcription and analysis. Participants were informed that they could withdraw from the interview at any time.

	Refused Interview			Interviewed	Total Respondents
	Closed	Busy/Unwilling	Unable*		
Patients	NA	1	8	28	37
Pharmacies	14	18	1	40	70
Diagnostic laboratories	2	5	0	40	47
Private Practitioners	0	0	0	38	38
Government officials	0	0	0	4	4

* Patients who were selected but expired prior to the interview. For pharmacies / laboratories, unable refers to cases where the individuals at these locations were not qualified to answer questions.

Chapter 3

Results and Discussion

3.1. Private Practitioners Providing TB Care

3.1.1. Quantitative study

A total of 424 formal PPs practicing in the study area were identified. These comprised 279 specialists and 145 GPs. None of the providers had formally registered for any existing PPM scheme with the DTO during 2011. However, informal engagement existed in the form of TB suspect referrals to DMCs for sputum examination. The analysis revealed that out of the total 424 PPs, 95 (22%) had made at least one referral in the year 2011. By category, 58 (21%) out of the total 279 specialists and 37 (26%) out of the total 145 GPs had made at least one referral during the year. There were a total of 675 TB suspect referrals from PPs. Specialists had referred a total of 344 suspects and the remaining (331) were referred by GPs. The median number of referrals per PP was 2, with an interquartile from 1-7. No major variation was observed in the referral pattern between specialists and GPs. Tables 6 and 7 respectively demonstrate the total number and proportion of PPs referring suspects to DMC for sputum examination, and the volume of referrals made by different categories of PPs.

Name of DMC	Population	Number of PPs					
		Specialists		GPs		All PPs	
		Total n	Referring n (%)	Total n	Referring n (%)	Total n	Referring n (%)
Koratagere	17,021	5	1 (20)	15	4 (27)	20	5 (25)
Kunigal	39,721	13	3 (23)	14	3 (21)	27	6 (22)
Pavagada	67,235	14	1 (7)	9	3 (33)	23	4 (17)
Sira	66,520	19	9 (47)	26	11 (42)	45	20 (44)
Tumkur-DTC	305,821	228	44 (19)	81	16 (20)	309	60 (19)
Total	496,318	279	58 (21)	145	37 (26)	424	95 (22)

The total number of TB suspects examined at DMCs in the study area was 4,446. PPs referred, in total, 675 TB suspects, contributing to 15% of all the presumptive TB cases examined at DMCs. Out of the total 4,446 cases examined, 678 cases were smear positive (15%). The number of sputum positives among patients referred by PPs was 157 (23%). Out of the 678 smear positive TB cases, 157 of them had been referred by PPs which thus contributed to 23% of the total smear positive TB case

detection. However, wide variations were observed across the different DMCs (Table 8).

Table 7: Volume of referrals per PP

Name of DMC	Volume of Referrals by PPs					
	Specialists		GPs		All PPs	
	Total n of referrals	Median n per specialist (Q1-Q3)	Total n of referrals	Median n per GP (Q1-Q3)	Total n of referrals	Median n per PP (Q1-Q3)
Koratagere	15	(-)	18	2 (1-11)	33	2 (1-15)
Kunigal	28	11 (3-14)	76	2 (1-73)	104	7 (2-29)
Pavagada	7	(-)	14	4 (1-9)	21	6 (2-9)
Sira	40	1 (1-8)	162	9 (2-30)	202	5 (1-12)
Tumkur-DTC	254	2 (1-5)	61	2 (1-6)	315	2 (1-5)
Total	344	3 (1-6)	331	2 (1-9)	675	2 (1-7)

**PPs who own a clinic and visit nursing homes as consultants*

3.1.2. Qualitative study

A total of 38 in-depth interviews were conducted with PPs. Table 9 provides the demographic characteristics of the respondents. The following sections describe the results using major themes that described the constraints in collaborating with the RNTCP.

Table 8: Total number of TB suspects examined and found smear positive

Name of DMC	Presumptive TB cases examined by sputum smear microscopy		Sputum smear positive TB cases		
	Total n	Referred by PPs, n (%)	Total, n (smear positivity rate)	Referred by PPs, n (smear positivity rate)	% of smear positive TB cases referred by PPs
Koratagere	511	33 (6)	55 (11)	5 (15)	9
Kunigal	379	104 (27)	50 (13)	16 (15)	32
Pavagada	1,244	21 (2)	215 (17)	12 (57)	6
Sira	1,174	202 (17)	184 (16)	56 (28)	30
Tumkur-DTC	1,138	315 (28)	174 (15)	68 (22)	39
Total	4,446	675 (15)	678 (15)	157 (23)	23

Table 9: Profile of PPs who participated in the interviews						
Code	Age	Sex	Place	Qualification	Facility	Collaboration with RNTCP
R1	58	Male	Urban	MBBS	Clinic	Active
R2	56	Male	Rural	BAMS	Clinic	No
R3	59	Male	Urban	MBBS	Clinic	Minimal
R4	56	Male	Rural	MD, General medicine	Nursing home	Active
R5	43	Male	Rural	MBBS, Diploma in child health (DCH)	Clinic	Minimal
R6	48	Male	Urban	MD, General medicine	Clinic*	Active
R7	57	Male	Urban	MS, General surgery	Nursing home	Active
R8	57	Male	Urban	MD, General medicine	Clinic*	Active
R9	61	Male	Rural	MBBS	Clinic	Active
R10	62	Male	Rural	MBBS	Clinic	Active
R11	49	Male	Rural	MBBS	Clinic	Active
R12	50	Male	Urban	MD, Physician	Clinic*	Active
R13	54	Male	Urban	MBBS	Clinic	Active
R14	47	Male	Rural	MBBS	Clinic	Active
R15	63	Male	Urban	MD, Physician	Clinic	Minimal
R16	54	Male	Rural	MBBS	Clinic	Active
R17	64	Male	Rural	MBBS, DCH	Clinic	Minimal
R18	49	Male	Rural	MBBS, DCH	Nursing home	Active
R19	54	Male	Rural	BAMS	Clinic	No
R20	50	Female	Rural	No qualification	Clinic	No
R21	49	Male	Rural	BAMS	Clinic	No
R22	43	Male	Urban	MBBS	Clinic	Minimal
R23	46	Male	Rural	MBBS	Clinic	No
R24	46	Male	Rural	MBBS	Clinic	Active
R25	65	Male	Rural	MBBS	Clinic	Minimal
R26	50	Male	Urban	Unani	Nursing home	Minimal
R27	63	Male	Rural	MBBS	Clinic	No
R28	48	Female	Rural	No qualification	Clinic	No
R29	55	Male	Rural	MBBS,DCH	Clinic	No
R30	55	Male	Rural	MD, General medicine	Clinic	No
R31	52	Male	Rural	MS, General Surgery	Nursing home	No
R32	57	Male	Rural	MBBS, DCH	Clinic	No
R33	50	Male	Rural	MBBS	Nursing home	Minimal
R34	50	Male	Rural	MBBS, DCH	Clinic	No
R35	49	Female	Rural	MBBS	Clinic	No
R36	49	Male	Rural	MBBS	Clinic	No
R37	39	Male	Urban	MBBS, Chest specialist	Clinic	No
R38	38	Female	Urban	BAMS	Clinic	Minimal

*(Bachelor of Ayurvedic Medicine and Surgery)

3.1.3. Diagnostic and treatment practices

PPs discussed the challenges surrounding the diagnosis of TB in general. They reported that it was difficult to diagnose TB (both pulmonary and extra-pulmonary) in the early stages because of varied clinical presentations, which may lead to a misdiagnosis of TB. Rural GPs and specialists univocally agreed that it was practically impossible to accurately diagnose extra-pulmonary and sputum negative TB cases, because of the lack of diagnostic facilities in rural areas. Non-involved GPs referred their TB suspects to specialists located in nearby cities for diagnosis and further management. Patients who could afford sophisticated investigations in private laboratories located in cities were found to use these services. However, patients who could not afford these services were found to reach government hospitals only when they were terminally ill.

PPs used a battery of investigations such as chest X-ray, ESR, total blood count, differential blood count, sputum examination, Mantoux test, etc., to diagnose TB, in their order of preference. The most common protocol used for TB diagnosis was clinical examination coupled with chest X-ray and blood investigations. There was a preference for chest X-ray, as it is rapid and results are obtained quickly. Patients were subjected to sputum examination if any parenchymal lesions were found in the X-ray. The use of sputum examination was solely dependent on the provider's preference. Actively involved PPs placed great trust on the technical competency of government laboratory technicians as compared to private laboratories and referred their patients to government DMCs for conducting sputum examination. However, there were instances when patients refused to go to government hospitals for sputum examination. Since PPs themselves were convinced about the quality of the services provided by the government laboratories, they took the extra effort to convince the patient to go to the government hospital.

An excerpt:

“Because they (lab technicians) will examine lot of patients daily... they would have seen so many slides every day. RNTCP technicians are very well trained. They invariably give good results. ... some people will tell that, they will go to private labs. Then we will tell them that, here (private lab) they will not do it. You go to government only. I never send my patients to private labs for sputum AFB. I will send only to the government”

*- R12, specialist, actively involved,
urban area*

However, the decision of non-involved and minimally involved PPs, both in urban and rural areas, to send patients to government or private laboratories heavily depended on the economic status of the patients. If they were well-to-do, they were sent to private laboratories and if poor to the government hospital.

“I will be knowing their financial condition. They will be visiting me quite frequently. I can make out whether they are affordable or not... then I will decide and send them. If it is unaffordable case, I will ask them to go to government and get the sputum test done. They will go.”

- R36, GP, non-involved, rural

Most of the involved doctors tended to follow RNTCP treatment guidelines. Non-involved and minimally involved PPs, on the other hand, tended to either sub-optimally treat patients for a duration of three months or overtreat them for a year and a half. The most commonly used Anti-TB treatment (ATT) was AKT3 and AKT4 on a daily basis. Some PPs used a combination of AKT4, AKT3, and other antibiotics as the first line of treatment.

3.2. Barriers for Collaboration

3.2.1. RNTCP functioning

PPs raised several issues with regard to the functioning of RNTCP, which hindered the collaboration between PPs and RNTCP. These concerns are discussed below:

No feedback from the RNTCP

Many PPs (not involved and minimally involved) mentioned lack of feedback from RNTCP as one of the reasons for not referring their patients. The program failed to provide them with any information on referred patients. It is natural that the treating physician would be interested in knowing about the welfare of his/her patient. For example, whether the sputum was positive or whether ATT has been started, and if started, what is the progress and outcome of the treatment, etc. There was no mechanism in the program to provide systematic feedback to the referring practitioners. However, the situation was different when the referred suspect turned out to be ‘sputum negative’. RNTCP did not bother about sputum negative patients, and they invariably returned to their treating physicians.

“Whatever TB patients I have referred to RNTCP, they have not come back to me. This is the practical problem of sending our patients to RNTCP. It is not only me. ...all physicians, everybody is feeling like that”

- R37, minimally involved, specialist, urban

However, the actively involved PPs differed on this issue. They reported that 90% of their referred patients came back to them to show the sputum examination results. After seeing the sputum results, the physician referred them to the nearby PHC for DOTS. They did not see any problems, right from the referring of patients to starting them on RNTCP treatment. It appears on the whole that the entire mechanism of feedback and counter-feedback depended greatly on the doctors’ rapport with patients and also on the PP’s confidence on the functioning of RNTCP. An excerpt:

“Actually, they (TB staff) will also tell the patient to show the sputum positive report to the referring doctor. Actually there itself they will tell. They will put a rubber stamp and they will advise patient to go to concerned referring doctor or nearby PHC. But patients will come back to us.”

- R12, actively involved, specialist, urban

Loss of confidentiality and related problems with DOTS

PPs, especially those practicing in rural areas, raised the concern that their patients hesitated to go to government hospitals for fear of being labeled as a ‘TB patient’ in their village, even though the RNTCP staff claimed to provide medication discreetly. However, PPs argued that this was not possible in reality and the confidentiality of patients was usually not maintained in the program. Another concern raised by the PPs, was that DOTS was usually provided at government hospitals. This was inconvenient to the patient in many ways: patients had to travel 2-3 kms to reach the PHC. Furthermore, they found this difficult as they were very sick. Other problems were overcrowding and the long waiting time to commence DOTS. Finally, patients felt uncomfortable being supervised by an unknown person while consuming the tablets.

Loss of credibility

PPs very strongly objected to the fact that when they referred their patients to the DMCs for sputum examination and they turned out to be positive, the RNTCP staff would turn them down. Moreover, they would persuade the patient to take only RNTCP drugs and ignore the suggestions of the treating physician. This confused patients and resulted in suspecting the PP’s intentions. PPs perceived that the actions of RNTCP staff could eventually lead to loss of their credibility in front of their patients.

“If we send the patient there and if it is positive, they will fall behind the patient and ask them “ why didn’t you come here directly, why your doctor is giving these private drugs, why your doctor is not giving free drugs....”like this. This will be embarrassing for patients. They will have doubts about why my doctor is doing like this”

- R37, specialist, non-involved, urban

Another PP from the rural area narrated how he lost his credibility in front of his patient. Suspecting TB in the patient, he referred the patient to the DMC. When the sputum test turned out to be negative, the patient was told that he did not have TB and was sent back home. This led to the patient losing faith in the treating physician and he returned to the same PP only after a year, by which time he was seriously ill. He was then treated with ATT, following which he recovered within a week.

Other PPs brought out the issue of drug shortage at government hospitals. There were instances where actively involved PPs had convinced their patients to go to government hospitals after emphasizing the availability of free and good quality

drugs. However, when the patients reached there, they were either sent back because of a shortage of drugs or asked to buy some of the medicines from a private pharmacy.

“But now a days, we have complaints that drugs are not available in the government hospitals. I have been hearing this past one or two years. Majority of the times, Streptomycin and Rifampicin are not available”

- R9, GP, actively involved, rural

Drug toxicity

Non-involved PPs frequently mentioned drug toxicity as one of the reasons for not referring their patients to the RNTCP. They mentioned it as the most common reason for patients refusing to go to government hospitals in the first instance. It was also the most often-stated reason why a patient quits DOTS drugs and switched over to private treatment. This problem may occur when PPs start the treatment with AKT4 (two tablets) to bridge the time gap from the time of diagnosis to initiation of DOTS treatment in the nearby PHC. The TB staff typically take a few days to complete the formalities to start DOTS. When patients switched from AKT4 to DOTS, they found it difficult to consume seven tablets all at once and sometimes developed severe gastritis. On the other hand, involved PPs argued that the lack of counseling before starting treatment was the reason why patients perceived drugs to be toxic. Hence, PPs called for intense health education to be imparted to patients before starting DOTS treatment. They argued that drug toxicity was present both with private and government drugs hence, these drugs must be supplemented with antacids and anti-emetics. These precautions were not usually taken at government hospitals.

An excerpt:

“In private, we usually give combination of tablets. In RNTCP they will give seven tablets. Most of the patients develop gastritis and they will be reluctant to swallow the tablets. The patients have to be counseled in advance that they will feel like vomiting and so for that they have to take these drugs. If that counseling is given, they can take it.”

- R31, specialist, not involved, rural

Delays in getting sputum examination results

PPs raised a concern about the high lead-time to obtain sputum examination results. When a patient was referred to the DMC, the staff did not collect the sputum on the same day. Instead, the patient was given a container to collect the early morning sputum sample and asked to report to the DMC on the next morning to provide the spot sample. On the next day, the patient had to wait till the afternoon to get the sputum results. In other words, the patient would lose two days in getting the sputum results. Hence, the PPs first preference for diagnosing TB was chest X-ray.

“First we will do chest X-ray, because sputum AFP takes lot of time. When patient goes there, they do not do it at that time. They will give a cup, and ask them to return next day. Patient have to collect early morning sample, go to hospital, give another one sample... wait for results till evening...”

- R37, specialist, minimally involved, urban

3.2.2. General health system issues

PPs raised several concerns with regard to the poor functioning of government hospitals that hindered the collaboration. PPs cited several reasons especially in rural areas, as to why they would prefer to send their patients to nearby cities for diagnosing TB. The first concern was that government hospitals were in general overcrowded. Government medical officers (MOs) had to attend to things which require immediate attention, such as women in labor, post-mortems, etc. Hence, a good clinical examination was not possible and they invariably overlooked the diagnosis. Though many PPs were in agreement with regard to the efficacy of the intermittent regimen practiced in RNTCP, they also were of the opinion that the quality of drugs available at government health facilities was poor. PPs also reiterated this stating that many of the TB patients would have sought care in the government hospital in the first instance but for the poor quality of drugs. Other factors reported for overlooking the diagnosis were poor quality of X-ray pictures and collection of poor quality of sputum samples at government hospitals.

Some PPs from the rural areas also raised concerns about the competency of doctors posted in the PHCs. These were either fresh graduates from medical college with minimum clinical exposure, or doctors trained in alternate medicine posted there with no training to practice Allopathy. When a patient with suspected TB was referred to PHC, the tendency was to perform only a sputum examination instead of combining this with other related blood tests. Another major constraint was the inability to diagnose extra-pulmonary TB cases due to the unavailability of specialists at government hospitals, as most of the specialist vacancies at government hospitals are yet to be filled. Another common reason cited was the unavailability of doctors or lab technicians. They were either absent from duty or busy with other engagements. Considering these lacunae and the uncertainty of diagnosing TB correctly at government health facilities, PPs preferred to refer their patients to nearby cities for laboratory investigations. These concerns were also echoed by some of the involved PPs.

“There are so many problems... non-availability of doctor or lab technicians. Many a times they do not respond properly. It is not only rich people, both poor and rich prefer private treatment”

- R4, specialist, actively involved, rural

Lack of trust between the two sectors was prevelant. PPs opined that the staff at government hospitals did not respect their clinical acumen. Staff at government

hospital were interested only in sputum positive cases. If a referred TB suspect turned out to be sputum positive, the response was immediate. However, sputum negative patients were neglected in spite of repeated suggestions from the treating physician. An excerpt:

“Government people have lot of ego. For sputum positive, they will start treatment immediately. But for sputum negative, they will never start the treatment. After roaming for minimum fifteen days, patient comes back to me. I have made several calls to taluk health officer. Then only they have started the treatment for smear negative cases. Even if I make diagnosis and if I send them with a request letter to government people will never start the treatment”

- R5, specialist, minimally involved, rural

“They do not accept the prescription given by us. For example, if we say that this case requires radiology, they will simply say that it is not required and also add that it is a simple respiratory infection. We prescribe some medicine but they will not accept it, they say that it is not good and prescribe something else”

- R27, GP, non-involved, rural

MOs in PHCs do not take care of TB patients in a holistic way. There was no counseling before starting the patient on the DOTS treatment. According to PPs, this was the main reason that patients stopped taking the drugs during the course of medication. When the patient developed some side effects because of the TB drugs, there was no mechanism to attend to these ailments. Even when a patient reached the PHC, the tendency of the doctor was to examine the patient as only a ‘TB patient’, ignoring his/her general physical wellbeing.

One PP raised the practical issue of developing a rapport with local government officials who get frequently transferred. As it took time and effort to build rapport with each other, this had a detrimental impact on collaboration.

“The problem is with the government officials is,.. each and every year, one or the officer will change. Making a reputation with the new fellow is very difficult. Second thing, see, I am a private practitioner sitting in my clinic and earning, I cannot go around to THO, offices, I cannot go behind them... I have to work here”

- R5, Specialist, minimally involved, rural

However, in spite of the limitations listed above, most of the involved providers referred their patients to government facilities both for diagnosis and treatment. PPs referred patients to the concerned PHC with a letter addressed to the MOs requesting them to start DOTS. They believed that their letters were usually honored by the MOs. Thus, it can be concluded that the nurturing of the association between PPs and

PHCs precipitated to the PP's confidence on the functioning of government health systems. If they were convinced about the quality, then they would automatically convince the patient to go to government hospitals. If they were not, they would not convince the patient to go to the government facilities and blame the patients for failing to do so.

Other categories of respondents such as policy makers and technocrats also echoed some of the concerns about government functioning and how it affected collaboration. Some opined that the DTO was overburdened with routine work and felt that PPM was an extra activity. Since there was hardly any active monitoring of the PPM program, the DTO did not implement it fully.

“DTO may think, why should I do unnecessary things which will bring more work on my table. If I get involved into this and that private practitioner, I have to report, account, and I have to check. Why unnecessarily all these pains?”

- Technocrat-3

This was further compounded by the frequent turnover of DTOs. Hence, even if one DTO signed a MoU with PPs, there was no guarantee that this MoU would be upheld by the next DTO. This confusion prevented PPs from getting involved. Currently, a large number of the PPMs are managed by the State TB Officer or Senior TB Laboratory Supervisor (STLS) who are non-medical people are not accepted by the PPs. On the other hand, the DTO do not take effort to change the opinion of the PPs, nor do the PHC MOs bother about it as they see it as part of the TB program and not ‘their’ immediate responsibility. The RNTCP also does not trust the sub-district officers and hence does not delegate this responsibility to them. This is a significant barrier to the development of PPM.

3.2.3. Other barriers affecting the collaboration

Fear of losing the patient

PPs hesitated to refer their patients to RNTCP. This is because they felt that once they referred patients to the RNTCP, they would definitely lose the patient forever. PPs were aware that the RNTCP had a good protocol for TB diagnostics tests and started treatment immediately if a patient was found to be sputum positive. Further, they also acknowledged that RNTCP performed regular follow ups to ascertain whether the patient was improving under the supervision of the DOTS provider. The availability of all these facilities within the system reduced the chances of the patient returning to their treating physicians. Thus PPs feared losing their patients and the associated revenue from them.

“I was not happy referring my patients to RNTCP. I missed all my patients whom I sent to RNTCP. I am practicing doctor. They have to come for follow up once in fifteen days. But here they never turn up until unless there is some serious illness like hepatotoxicity or severe gastritis”

- R37, specialist, minimally involved, urban

However, PPs from rural areas argued that they did not take any consultation fee for the follow-up visits from TB patients, who were usually poor. They argued that they were not referring patients since they were not convinced about the functioning of the government facilities. They reiterated that, there was no fear of losing income from TB patients.

On the other hand, technocrats and policy makers opined that, PPs generally resisted involvement with the government, because PPs perceived any collaboration with the government to be linked in general with some controls and regulations. Since the government has the power, they could enter private hospitals without any notice under the pretext of collaboration. Practitioners did not want to invite trouble just because they had two or three TB patients. When the government approached PPs, they did not, in general, explicitly refuse the engagement with RNTCP. However, there was always the element of losing income and they would counter the engagement, by challenging the effectiveness of the intermittent regimen, quality of drugs, etc. One of the officials involved with engaging PPs expressed this concern.

“It was a mix of controversies that touched upon dosage, whether daily regimen, intermittent regimen, all kinds of things... but this had an element of losing income also. So it was very difficult to separate out the causes. Even if you convince the people on all other technical reasons, still the people were not interested...which was financial interest...”

Technocrat-1

Changing practice behavior depending on the location

Some practitioners teaching in medical colleges tended to behave differently depending on the location of practice (medical college or own clinic). They practiced DOTS when they were in the medical college but tended to put their patients on private TB treatment when they were in their clinics doing private practice. One respondent, who taught in a medical college, listed a series of reasons why he did not want to practice DOTS in his clinic: loss of patients, pill burden, poor quality of drugs, and dislike of direct observation of treatment and did not want his patients to stand in the long queue.

Difference in ideologies

Some PPs felt that this PPM arrangement would not work at all. They reiterated that, the public and private were two different entities, which worked in entirely different fashions with different ideologies. Thus, if the government tried to involve PPs in the program, it would never be a success. Instead they suggested that PPs be trained in standard treatment guidelines. They felt that they were competent enough to treat their patients.

An excerpt:

“If we are made to get involved with government, it will never workout. It is not possible to work with government. None of the government programs will progress with this approach”

- R27, GP, non-involved, rural

This was also echoed by technocrats, who said that the program had to understand the difference in the motivations of the public sector vs. the private sector for effective collaboration between them. They argued that the logic and dynamics of the private sector was very different from the government. PPs needed patients and they were not very interested in public health. That was why PPs raised various objections and stayed away from the RNTCP. For example, the diagnostic modality adapted by the RNTCP strongly emphasizes on sputum examination, which is not at all attractive for PPs. They preferred the quickest way to diagnose either by using X-ray or serology. As serology is now banned, they have moved to IGRA (Interferon-Gamma Release Assay). For a PP, it was most important that his/her patient's symptoms get resolved in the quickest and easiest possible way. Additionally, there were business propositions which were very much inherent to the private sector. For instance, if a patient was economically well off, the practitioner would prescribe sophisticated investigations such as CT or MRI scan. A rich patient would not mind paying for such tests, but poor patient preferred tests that were as cheap as possible. Taking these dynamics into consideration, PPs argued that it was difficult to fix an amount as an incentive for referring the patient to RNTCP.

Another important factor for the reluctance of PPs in joining government programs was the loss of income from kickbacks. There were certain hidden sources of revenue if a doctor was performing a CT scan for diagnosis. If the program required the practitioner to perform the diagnosis based only on sputum smear, he/she stood to lose INR 2000 to INR 3000 as kickbacks. This could not be compensated under the program. If corporate hospitals or bigger practitioners were considered, the diagnostic tests ordered by them and other items were not even under the control of the practitioner. Hospitals have policies regarding the percentage of the patients undergoing procedures such as a CT scan. These are issues that were outside the purview of the TB program.

Dilemmas of specialists

It was expressed by a specialist that, it was much more difficult for a specialist to make a choice whether to send a patient to the government program or not, as it has an implication on his/her professional relationships with other doctors. This is because specialists tend to get referred cases from their peers. Hence, they also have to consider the preferences of the referring PP for their own survival. One specialist narrated a situation where his reputation with his colleague turned sour after he referred a patient to the government hospital. An excerpt:

“A military TB case was referred by a doctor. I told patient that he can take treatment either in government or in private. They went to government and did not return to the referring doctor. That doctor felt bad that I misled the patient. He questioned me, ‘why you referred my patient to government sector, we missed the patient’”

- R37, specialist, minimally involved, urban

Unnecessary paper work

For many PPs, getting involved in any government program meant a lot of unnecessary paper work. They mentioned that the time to compile such reports or attend any such meetings was not possible in the private setup due to lack of time. Some also felt that a lot of patients had started seeking care from private hospitals after the government had implemented many Public Private Partnership (PPP) programs such as in Reproductive and Child Health (RCH). They found it difficult to handle the huge amount of patients which were diverted from government hospitals. Hence, they preferred rather to refuse collaboration than to get into a difficult situation. They were ready to make referrals on an informal basis without entering into any formal arrangement. One PP who has referred all his cases to RNTCP said,

“I am happy with this arrangement of referring my patients to RNTCP. I always refer my cases to RNTCP. It is easy for me as I don’t have to do any paper work. If I were to do any paper work, then I would have thought about it mostly. I don’t want any paper work and any headache.”

- R1, GP, actively involved, urban

3.2.4. Problems with existing PPM guidelines

Some respondents felt that the PPM guidelines were primitive and designed by the government with the intent of protecting the interests of one party, i.e., themselves. For an effective partnership, the role of both parties should ideally be distinct, which was lacking in the case of PPM-TB. Improvements were suggested by a few technocrats and policy makers, which are discussed below:

Inability to address the diversity and complexity

India has a variety of private health providers of various sizes and functions. It ranges from informal providers, non-allopathic practitioners, individual allopathic practitioners, nursing homes, bigger hospitals, corporate hospitals, etc. PPM guidelines developed by the GoI do not address this diversity. Specialists in general medicine or a chest physician treating a TB patient may receive monetary incentives in thousands of rupees. However, a GP might receive only a few hundred rupees. One practitioner cannot receive thousands and another merely hundreds. Hence monetary incentives alone will not work. Although there are successful models based on the PPM guidelines, these have not been scaled up. These guidelines were developed based on evidences from small projects. If financial incentives are to be considered

solely for involving the providers, then it has to be adjusted to the local contexts. An excerpt:

“you give INR 25 for a referral of the TB suspect. One should think whether this INR 25 has any value. In Calcutta city, you can get a meal for INR10, which you cannot get in another city. This INR25 also has different kinds of values. In a state like Kerala, INR25 is nothing... because the daily wages of a manual labor is INR 800. So, in such a place, if you are telling a doctor that I will give you INR 25 (laughs)...so incentive wise it is not attractive at all”

- Technocrat-2

Straitjacketed approach of RNTCP

It was discussed that RNTCP had a straitjacket approach and there was a need to make it more flexible. One technocrat asked ‘why do people have to listen only to WHO recommended regimens?’ He recommended that the present DOTS regimen be liberalized to a broader regimen. This concern was also echoed by an official who felt that the current PPM schemes were indeed very restricted and did not offer much flexibility to PPs. These regimens should be developed by involving other stakeholders, such as pharmaceutical companies. These companies should be encouraged to suggest a few more options, rather than the existing narrow options. The government should then suggest both from the perspective of the private and the government sector that there were a couple of regimens which PPs could choose to use. However, there is a cautionary note that the International Standards of TB care should be adhered to while using these different regimens.

3.3. Why Some PPs Refer Their Patients to RNTCP

All involved PPs were asked the following questions: how did they know about the RNTCP, when and why did they decide to refer their patients to the RNTCP. One thing they had in common was that they had either undergone formal RNTCP training or attended sensitization programs organized by the IMA or RNTCP. This was followed by frequent visits of the RNTCP field staff to their health facilities, requesting them to refer TB suspects to RNTCP. PPs gained confidence in the program when laboratory technicians started reporting AFB (Acid-Fast Bacilli) positive in the sputum examinations. One provider, who received an award from the district administration for referring the maximum number of cases, narrated how the collaboration happened.

“TB patients who used to come to me were usually poor and the village patients never used to complete the treatment in spite regular counseling. That was the main drawback with our private treatment. Many times, we were not sure whether they were taking the medicine or not...but with RNTCP, we are sure they will ensure the completion of treatment of our patients.

When I started sending to RNTCP, we started getting many AFB positive cases. RNTCP people were quite happy with our referrals. They themselves were approaching us, they used to give us referral pads, give feedback of sputum results”

- R24, GP, actively involved, rural

The perception about the functioning of the RNTCP was generally good among involved PPs. Rural PPs referred their patients to government facilities because the TB treatment was free there. However in urban areas, the reason for referral was for regular follow ups under RNTCP to ensure adherence and completion of treatment. PPs expressed that some patients refused to go to government hospitals because of the negative perception of the quality of care provided there. However, PPs believed that the onus was on the treating physician to build confidence and motivate them to go there. It appeared that if the PP was convinced about the functioning of the RNTCP, he/she would be able to send his/her patients there. One PP narrated how he convinced some patients who refused to seek care from the government hospital:

“It is how we convince them that makes the difference. The patients believe us, they trust us... I tell them that they would get a better report there. I will also tell them that it will be done free of cost. I confirm that the report is very accurate there because they are well-trained staff and so the report is better there. We have not sent a single case outside the government hospital for sputum AFB”

- R24, GP, actively involved, rural

However, some minimally involved PPs referred patients to the RNTCP, just to get rid of them. This attitude was observed both in the urban and rural areas. When PPs felt that they could not ensure completion of treatment and when patients kept bothering them with small ailments, they referred them to the RNTCP in order to get rid of them.

“When patients don’t take the medicines properly, we will feel why to take the risk? Anyway, these TB staff keep telling that they give free medicines. So, let them go there. Hence I send such patients to the government so that the ASHA workers will take care of it there”

- R33, GP, minimally involved, rural

Similarly, a busy GP practicing in the urban area, having around 150-200 outpatients /day, may not want to treat any TB patients in his/her outpatient department (OPD). They perceived TB patients as a nuisance, who would require lot of health education and counseling. Also, they did not have either patience or time to do so. Hence, they preferred to get rid of them by referring them either to a nursing home or government hospital:

“that’s why I send them there (DMC)...so that they don’t come back to me again”

- R3, GP, minimally involved, urban

Among informal providers, those having smaller clinics referred TB patients to RNTCP because (a) treatment is free there, (b) they do not have adequate knowledge

about TB treatment, and (c) TB patients may spread infection in their OPD. However, those who had their own nursing homes preferred to retain the patient and treat them by themselves.

3.4. Awareness About RNTCP and PPM Schemes

Implementers did not have a clear idea with regard to ‘what is PPM’. When the question was asked about the performance of PPM, respondents instead pondered around the question, ‘what is PPM-TB in India’? TB-PPM was designed, not only to involve private sector providers, but also to involve public sector undertakings (prison, defence hospitals, etc.). It was intended for public-public, public-private, and private-private partnerships. Among these, the only major success the program has had is in the involvement of medical colleges.

Lack of awareness among TB patients about the disease was seen as one of the major problems in controlling TB. Many understood the main objective of PPM-TB to be ACSM. They were not aware of the existing PPM schemes for PPs in particular and also the guidelines for involving them in various schemes. Their perception of the involvement of PPs in the program was limited to the making of PPs DOT providers and providing them with an incentive of INR 250. The concept of collaboration with PPs was limited to referrals of TB suspects to DMCs. An excerpt:

“we have given them training in the beginning of RNTCP in 2007-2008. We have requested them to do referrals to us. Based on that, they are sending the suspects for diagnosis. We are giving DOTS drugs to those doctors only. Apart from this there are no other schemes for them”

- Implementer-1

All the specialists interviewed in the involved category were trained in RNTCP. They also got themselves updated with regular CMEs (Continuing Medical Education) conducted by the IMA. GPs in urban area had come to know about RNTCP from a sensitization workshop conducted 3-4 years previously by the DTO. Others had heard about it informally through friends working in government hospitals. Most of the informal providers had undergone one day RNTCP sensitization program, several years earlier. They felt that they had learnt more about RNTCP through patients, ANMs (Auxiliary Nurse Midwives) and ASHAs (Accredited Social Health Activists) than through training. None of the non-involved PPs interviewed were trained in RNTCP. They were skeptical about the efficacy of intermittent regimen practiced in the RNTCP. They reported that they still practiced the daily regimen as articulated in medicine textbooks. They had not heard about any standard treatment guidelines.

Apart from one provider, none of the PPs interviewed were aware of the existing PPM schemes. Even the PPs who had been regularly referring TB suspects to RNTCP were not aware of the schemes. One specialist who had been actively involved with the RNTCP was not aware of the PPM schemes. When the researchers explained about the existing schemes, he exclaimed ‘I myself did not know it means, how others will

know about it’, flagging the urgent need for information dissemination among the medical fraternity. Many PPs stated that the referring of TB suspects and providing DOTS were the only two tasks, which they could do in their routine practice. They did not see any utility in the other PPM schemes.

3.5. Training

It was found in general that those PPs who had undergone formal RNTCP training and had worked in the government sector previously were convinced about the DOTS strategy and had been referring cases there. It was found that none of the non-involved PPs had undergone any kind of RNTCP training. PPs were not referring cases, because of the lack of awareness about RNTCP. The critical need to train the non-involved PPs before approaching them for collaboration was emphasized. An involved PP said, ‘we have got the confidence in RNTCP because of training itself.’ Hence PPs should be trained in RNTCP to involve them in the program. Some minimally involved PPs stated that they had some information about the RNTCP, but it was insufficient and hence hesitated to send their patients there.

3.6. Interaction Between RNTCP and PPs

All involved PPs reported that the RNTCP field staff visited them often and they had good rapport with them. Minimally involved ones reported that the RNTCP staff had visited them once or twice, but only for a few years. However, non-involved PPs expressed that they had never been contacted by RNTCP. It appeared that the RNTCP staff tended to visit only those PPs who had referred cases to RNTCP. They visited these PPs to provide feedback, referrals slips, etc. There were minimal efforts to reach out to the non-involved PPs. One leading physician who is not involved said:

“they had come here about 4 to 5 years back and I had sent 2 or 3 samples. After that I have never seen them”

- R30, specialist, non-involved, rural

It was also true that PPs, especially those owning clinics, were not very familiar with government hospitals and their functioning. They did not know about the availability of full time laboratory technicians to perform sputum examination and doubted their technical competency. Some PPs without any ‘contacts’ in the government hospital wondered whether they would be respected if they sent any patients there. The main reason for such a situation was cited as lack of interaction between the providers (non-involved and minimally involved) and the government. However, they had been interacting with local NGOs to send HIV suspects to ICTCs (Integrated Counseling and Testing Centers) situated in government hospitals.

3.7. Opinion on Financial Incentives

PPs practicing in the urban area, especially specialists were not interested about the financial incentives offered by the program. They felt that they treated patients who were well off and hence were not in the need of any incentives from the government.

“No, we are not worried about that. We are not asking incentives or remuneration. They are giving like fifteen or twenty rupees. Nobody is bothered about the incentives to treat tuberculosis patients”

- R37, specialist, minimally involved, urban

The majority of rural practitioners also stated that there was no need for incentives to refer TB patients to the government hospitals. PPs with good practices reiterated that they took good care of their patients and if these got cured under DOTS, they would bring some more patients to them. This was also associated with getting social recognition in the society, which they perceived to be more important than monetary gains. They repeated that they did not look at TB patients as a means to make money. An excerpt:

“I don't get much revenue by TB patient... (his facial expression changes and he was not comfortable with this question).

I can get consultation fees of rupees 100 only. In fact, many TB patients are poor. Many times, I return the consultation amount to those patients who are very poor. I ask them to buy eggs from that money...I am not bothered about the income from TB patients...”

- R4, specialist, actively involved, rural

However, some others from the rural area welcomed the idea of incentives as it was given by the government and they felt that no one should lose the opportunity of extracting money from the government.

“We are paying tax to the government. They are paying our own money. We should not leave what comes from the government. If they give money for treating TB, we will take it”

- R35, GP, not involved, rural

Other PPs though welcomed the idea of incentives. They suggested that it would be a good idea if the program honored PPs who refer patients. In their opinion, providing them with social recognition would have long lasting effects.

“I don't get any incentives. But DTO has honored me in one of the TB day function, as I am referring many TB cases. It feels good. It encourages me to refer more cases”

- R1, GP, actively involved, urban

3.8. Informal Providers

Informal providers were not willing to reveal any information about the TB patients treated by them. This apprehension was because of an order issued by the government informing PPs not to treat any TB patients, but to refer them to government hospitals. However, on further probing, some of them revealed that they had been treating TB patients. They reported that after the launch of RNTCP, the number of TB patients treated by them had drastically reduced. Providers owning nursing homes had diagnostic practices similar to formal ones. They conducted all TB investigations in

laboratories attached to their hospitals (X-ray, sputum examination, Mantoux test, blood test (complete blood count, ESR and peripheral smear)). They even ordered sputum culture when the symptoms did not subside with ATT and eventually referred the patient to a specialist. The main source of information on TB drugs was through medical representatives. The treatment regimens followed by them were sub-optimal extending between two to three months. Although they claimed to take opinions from physicians to treat TB patients, their knowledge about the treatment was poor. They felt it was a privilege to get involved in the program as their practice would be legitimized. Many of them believed that it was illegal to treat TB patients and thus did not keep any record of TB patients.

3.9. Private Sector Dynamics and Expenditure Analysis

The researchers sought to identify the total cost of health care for a TB patient and the total earnings of a private practitioner providing TB care in order to evaluate the current model of incentivizing and its practical value. Individuals involved in each of the major components in TB treatment were interviewed to gauge their estimates of the costs involved as well as a broad overview of the private market for TB services in the state of Karnataka. As mentioned previously, all interviewees were classified based on their location as rural or urban. These categories were then further subdivided according to the type of respondent in order to discover the finer nuances within each of these setups.

3.9.1. TB patients

The perspective of patients provided the most comprehensive overview of the health care ecosystem for TB care. However the complexity of their experiences, the inability to separate TB related and unrelated health care issues coupled with recall bias made it difficult to extract accurate suggestions applicable specifically to TB programs. This was particularly true among rural populations who happened to make up the dominant proportion of the respondents in this study. Table 10 outlines the demographic profile of the TB patients included in this research.

Of the 28 patients surveyed, 11 patients had pulmonary TB, while the others (17) had extra-pulmonary TB. 24 patients out of the 28 had first sought care in a private health facility (either clinic or hospital). Of the others, three had tried home remedies first. Only one patient went directly to a government facility. TB was not diagnosed initially, resulting in the seeking of care from many providers. The median number of providers consulted by the patients was three, with a range of 1-5 (Table 11). Out of the 28 patients, 20 patients were referred to the government facilities by the private provider. However, only nine patients followed this advice and shifted to the government facilities, the remaining 19 continued to take treatment in private facilities even though it was costlier. The main reasons for this were the not so good

past experiences with government health facilities, inconvenient timings, and the rude behavior of the government health staff.

Patients interviewed in the study reported spending between a total of INR 3,600 to INR 43,000 on consultation, admission, diagnostics, and medicines. Those who sought care in the government facilities spent less (close to INR 3000 or USD 50). The cost of medications was seen as a significant burden by the patients and sometimes also became a factor in choosing to obtain treatment from government facilities where medicines were provided free of cost. However, because of the piecemeal nature of the purchases, patients were unable to reliably estimate their expenditure on drugs as a proportion of their total health care expenditure. Patients tended to quote a lump sum when asked about their total burden, which included most of the direct spending, but neglected to estimate indirect costs such as travel or loss of income.

Characteristic	Type	Number of Patients
Location	Rural	21
	Urban	7
Sex	Male	11
	Female	17
Age	21-30 years	8
	31-40 years	4
	41-50 years	4
	51-60 years	2
	>60 years	7
Occupation	Business	4
	Laborer	5
	Service	2
	Housewife	8
	Student	2
	Farmer	3
	Unknown	4

Number of facilities visited by a TB patient for diagnosis and treatment	Number of TB patients
1	5
2	4
3	12
4	6
5	1

3.9.2. Private diagnostic laboratories

Private diagnostic laboratories were further classified based on their size as small or big. The primary criterion for this distinction was the number of technicians employed. Small laboratories typically had only one staff member, whereas big laboratories employed three to more than ten members. Out of the 40 private diagnostic laboratories interviewed, nine laboratories were attached to hospitals. There were more laboratories classified as big in urban centers and these tended to be larger than the laboratories classified as big in rural areas. Big laboratories in general tended to be better equipped in terms of infrastructure, equipment, and the variety of tests performed. However, most laboratories, regardless of size collaborated with each other either via references or by collecting samples to be sent to other laboratories.

All laboratories (both urban or rural) performed basic tests such as blood counts, ESR, urine tests, and other diagnostic tests. Tests for dengue, malaria, and hepatitis were more common in urban laboratories. The most common diagnostic test for TB across regions was the sputum examination for AFB. In rural areas, government health facilities tended to have a big presence, particularly with respect to TB care and therefore laboratories reported encountering fewer TB cases and reduced capacity for TB diagnosis. For instance, a technician from a rural area reported "... the contract has been taken over by the RNTCP. So only government hospitals do that (TB diagnosis)." However, a number of laboratories, especially the larger ones in both urban and rural areas, did have the capacity for TB specific tests, such as Mantoux. They also reported the usage of ESR or other blood counts and X-rays as common tools employed by doctors to diagnose TB, indicating that they routinely dealt with diagnosing TB suspects. A relatively few laboratories had the ability to carry out cultures or serology. Often laboratories collected samples to be sent to larger laboratories (usually in cities) for culture. IGRA was rarely used in general as well as in the context of TB, in the areas surveyed.

Most technicians adjudged the sputum exam as the best test to diagnose TB when asked if they preferred certain TB tests over others. However, they also indicated that the sputum test was rarely the sole determinant for diagnosing TB. As one technician put it, "*The first best test is the sputum test. Second best test is the X-ray. The third test is the Mantoux test.*" However, labs, rarely if ever, influenced the choice of test that was carried out. Decisions regarding the test to be performed were entirely in the hands of the medical practitioners.

None of the laboratory technicians interviewed in this study, regardless of size or type or location, reported having any specific training for diagnosing TB. Most technicians had undergone general training to be a laboratory technician and some seemed to be learning on the job. None of them felt equipped to choose between the various diagnostic tests available and relied entirely on the doctors' prescriptions to determine the tests to be conducted. As a technician from a big urban laboratory said, "It is not

patients preference, what doctor say that we prefer, it is always based on the doctors instruction.” In rural areas, PPs tended to prescribe only basic blood tests and patients who were suspected to be suffering from TB were referred to government health facilities that seem to be the primary care providers for these patients. Laboratory technicians were uniformly agnostic about the profile of the practitioners who referred patients to their laboratory, except where these laboratories were attached to a hospital. Practitioners who referred cases to laboratories were a mix of general physicians, specialists, alternative practitioners (Ayurvedic /homeopathic), or even informal providers.

Most of the PPs in both urban and rural areas eventually referred TB suspects to the nearest government health facilities for treatment. However, government facilities were much more relied upon in rural areas compared to urban areas. The perceived cost of treatment was a major factor in patients being referred to the government facilities as laboratory technicians repeatedly referred to the free treatment available at government facilities for TB patients. Urban PPs typically prescribed more diagnostic tests and retained patients for longer periods of time before referring them to government facilities. The typical course of treatment as estimated by the laboratory technicians ranged between 3 to 9 months for both urban and rural areas.

Diagnostic costs seemed to be a relatively small chunk of the expenditure incurred by TB patients and were not seen as debilitating costs by either the patients or the laboratories carrying out these tests. Often laboratories reported discounting the cost of tests for poorer patients based on their discretion. Table 12 lists the cost of various diagnostic tests for TB carried out at these laboratories and the technicians’ perception of the typical total cost of diagnosis for a TB patient.

Most patients visited laboratories for TB diagnosis only on a doctor’s reference. Self-referral was mostly reported for conditions such as diabetes or blood pressure, and rarely for TB. In a few cases where the patients were reported to have come directly to the laboratories without a doctor’s referral, the reasons were trivial such as a holiday at the government laboratory or the urgency to obtain report.

The seriousness of the medical condition associated with TB was well appreciated with many of the technicians describing the symptoms, the association with smoking, and other risky behavior as well as the communicability of the disease. The laboratory technicians repeatedly pointed out the availability of free TB treatment available at government facilities vis-à-vis the heavy expense that would be incurred at private facilities.

3.9.3. Private pharmacies

All except three pharmacies included in the study were stand-alone stores unattached to any health facilities. The average number of patients visiting rural pharmacies was found to be 76 per day, whereas in the urban sector it was found to be 69 per day. All pharmacies stocked medicines for most common ailments such as cold, fever, and

hypertension. Pharmacies tended to stock anti-TB drugs and were able to list some common ones such as AKT3 and AKT4, despite their perception that the number of patients who purchased TB drugs was very low. The choice of which medicines to stock was determined by doctors' prescription patterns, opinions of company representatives, and the profit margins associated with each drug.

More than 71% of pharmacists in the rural sector said that they either never had patients come in for the purchase of anti-TB drugs or that this rarely occurs. In the urban sector also, 69 % of the pharmacists reported never having customers purchasing anti-TB drugs. Most of them believed that this was due to the fact that anti-TB drugs were available free of cost at government facilities. Table 13 lists the cost of TB medications as assessed by the pharmacists included in the study.

Cost of Diagnostic Test in INR (Average among respondents)	Urban Small	Urban Big	Rural Small	Rural Big
Sputum examination for AFB	50-150 (99)	50-200 (113)	20-100 (70)	40-300 (96)
Mantoux	50-150 (86)	40-60 (43)	NA	200 (n=1)
Sputum culture	200 (200)	150-300 (200)	100-200 (150)	150-250 (195)
Serological tests for TB	650-1000 (883)	200->1000 (733)	40-150 (95)	NA
Blood Tests (ESR, CBC)	30-250 (65)	30-50 (40)	30-50 (32)	25-40 (45)
Interferon test	NA	200 (n=1)	NA	NA
Total Cost of Diagnosis*	550 (~USD 9)	150-1000 (~ USD 2.5-17)	100-200 (~ USD 2-4)	110-120 (~ USD 2-3)

NA- Test not carried out

*Few respondents, often uncertain. Mostly based on perception.

Pharmacists were divided when asked to assess the affordability of anti-TB drugs with some deeming them to be affordable and almost an equal number stating that patients were too poor to afford them. Many private pharmacists both in urban and rural areas described the typical profile of TB patients as old and financially weak. More than 88% of the pharmacists noted that none of the TB patients purchased the entire course of medication at the same time. They bought the medications as and when they had the money to buy them. In a few cases (where the patient was a daily wage worker) they either purchased medication every day or as and when they had the required money. A respondent said, *“They are daily wage people. They have to work daily. They get the money in the evening, hence they come here in the evening and buy the medicines”*. Another pharmacist stated, *“Some patients buy for one month and some others buy for 15 days and some will buy full dosage for a week.”*

A mix of providers, such as qualified PPs, AYUSH providers, and quacks referred TB patients to these pharmacies. Most of the pharmacists said that they did not have the knowledge of the consultation fee of the PPs or the total cost of anti-TB drugs. However, the ones who were able to give an estimate stated that the consultation fee ranged anywhere from INR 30 to INR 300 per visit. Urban pharmacists provided higher estimates as compared to rural pharmacists. The perception of the total cost of health care for a TB patient was also slightly higher among urban pharmacists than rural ones.

In addition, these pharmacies reported cases of self-referral, particularly among the economically poorer sections. These patients did not see value in paying an additional cost to the doctor as consultation fee and purchased medicines based on the pharmacist’s recommendation to obtain symptomatic relief. According to one of the pharmacists, the patients also believed that the “*pharmacists have experience and that they know what is best for them.*” Thus pharmacists in the private sector can sometimes double-up as primary care givers, especially in poorer communities.

Category (Average among respondents)	Urban	Rural
Cost per day (INR)	10-14 (14)	5- 26 (12)
Cost per month (INR)	300 – 3000 (500)	150-2400 (360)
Cost of nutritional supplements (INR)	108(n=1)	-

3.9.4. Private Practitioners

PPs who were less involved with the RNTCP quoted higher figures for both TB diagnosis and treatment than actively involved PPs. However, the initial consultation fee for actively involved PPs seemed to be higher. When asked to estimate the costs involved for a TB patient, PPs put the total cost of health care for a TB patient at around INR 5000, which was far lower than the typical spending reported by patients. In addition to the initial diagnostic tests, PPs also reported prescribing X-rays or blood tests periodically to monitor the progress of their patients. Sometimes PPs, especially from the ‘not involved’ category also asked for HIV or insulin tests in private labs. Table 14 shows the breakdown of the direct costs involved in TB care, as perceived by PPs.

Cost of Diagnosis and Treatment (Average Among Respondents)	Actively Involved PP	Minimally Involved PP	Not Involved PP	Informal PP
Diagnosis (one time) in INR	150-400 (225)	275-500 (358)	70-800 (428)	500 (n=1)
Recurring Costs				

Consultation fee in INR	100-200 (150)	50-60 (54)	30-70 (48)	Unknown
Drugs (per day cost) in INR	10-34 (20)	9-65 (30)	13-60 (30)	Unknown

3.9.5. Commission/Kickbacks

Medical practitioners are the primary and often the only determinants of the choice of diagnostic tests and medications, and hence wield considerable power. One indication of this is the practice of kickbacks that these providers obtain from laboratory technicians and pharmaceutical companies. Respondents in this study hesitated to talk about this issue, but it was clear that this practice was very much a part of the private health care system. When posed with this question, PPs refused to admit to receiving kickbacks and some specialists were even offended by the question. However, on further probing they revealed that in urban areas private laboratories give a cut of around 5-10%. For TB investigations, they perceived that the cut provided by laboratories were meager when compared to the kickbacks provided in larger cities such as Bangalore, where the cuts were as high as 30-40%.

“Nothing, they are just doing for the sake of it.... It is not like Bangalore where they give 30% or 40%. Here they like 5 or 10%... it is nothing” - minimally involved, specialist, urban.

PPs estimated that they would earn around INR 3000-4000/patient during the course of treatment. This included any consultations and commissions they may receive. It appeared that the phenomenon of kickbacks was a norm in the private sector and available even to unqualified informal practitioners. An excerpt

“that is usual no madam... For X-ray, they give INR 120/patient referred. For sputum examination they charge 50-60 rupees/ patient. So hardly we get anything there. Pharmacies...-not really... they give us some gifts sometimes. You know how it works”
- Informal provider, non-involved, rural

All the pharmacists categorically denied paying any commission to the doctors. However, during the course of the interview, a pharmacist said, “*Lot of companies are giving the offer. If the doctor prescribes one medicine they get 30%. If they prescribe another medicine they get 40%*”. PPs tend to receive kickbacks from drug companies, especially if they have pharmacies attached to their health facilities and the practice is fairly widespread. Another pharmacist confirmed, “*... every clinic and nursing home will have its own medical store. The doctors will have the medicines which they want and person who will be there (in pharmacy) is also a doctor’s person only. They will ask them (patients) to buy medicines next to their clinic only and ask them to show the medicines. They scare patients. They say that they will get into problem if they buy*

tablets from outside and it is their headache afterwards. They show authorities on the patients to buy there only. This is because of the simple reason, they lose the commission if the patient do not buy there. If a patient buys INR 100/- worth medicine, we get only INR 15/-. Whereas, they get INR 40/- as commission and plus the medical store profit of INR 15/- to INR 20/-. So, they get 50% benefit.”

However, the existing data proved inadequate to discover the exact mechanisms by which kickbacks were doled out and the role of the pharmacists in this process, since more than 90% of the pharmacists included in the present study were attached to stand-alone stores.

About 30% of all the laboratory technicians surveyed also explicitly confirmed the payment of commissions to providers. A fair number pleaded no knowledge of this practice and about 40% denied any such payment from their laboratories. Some laboratories suggested that they were too new or too small and therefore had avoided having to pay these commissions. Others only paid commissions to practitioners who were situated far away from the laboratory or who followed up with them. Thus kickbacks have become a part of the system adapting to the local dynamics of the market. The amount of kickback paid seemed to be similar (between 20-40%) in both urban and rural areas suggesting that this practice was well-entrenched throughout the health care system. One big urban laboratory even confessed to maintaining systematic ledgers for this purpose, and also to receiving kickbacks from companies for purchasing their diagnostic kits. “We maintain a ledger. The accountant will tally it. Later we credit it to the account.”

Although there were no big differences between urban and rural laboratories in the payment of commissions, it appeared that this practice was not as widespread for government providers in the study area. Although more data is needed, it appeared that in small rural areas where government facilities were highly regarded and had considerable influence, fewer private laboratories reported paying kickbacks. Within the urban areas, however, fewer laboratories in Tumkur city explicitly confirmed paying kickbacks compared to those in Bangalore city, which is much larger and more urbanized.

3.9.6. Total cost of TB care

Each category of respondents was asked to estimate the total spending of a patient towards TB care. A wide variance was found between their estimates. Even within a given category of respondents there was not much uniformity in the perceptions of the total cost involved. This indicated that there was very little communication among the different kinds of service providers in the private sector and hence not much awareness of each other’s practices. Based on the estimates provided by each category of respondents, of costs involved in their own sector (e.g., diagnostic costs from laboratory technicians, consultation fees from PPs, etc.), the researchers attempted to arrive at the total costs involved for a TB patient (excluding indirect costs), and the total earning of a PP from such a patient. Most PPs retained patients for at least 3

months and often for up to nine months or more. A conservative estimate of the costs involved for six months of care was estimated (Table 15). The median spending on health care reported by patients in this study was INR 11,000 (~USD 180).

However, most patients visited multiple PPs (Table 11) and extended the treatment for a protracted period of time. Every time patients moved to a new PP, they would be asked to undergo fresh diagnostic tests, usually at a laboratory recommended by the PP. Drug costs would also correspondingly vary leading to several patients spending more than twice the amounts estimated here. Besides these, patients spent a considerable amount on transportation, food, and other indirect expenditure. The data gathered from PPs also suggests that there was a significant financial incentive for PPs to prolong the treatment of the TB patients who visited them and prescribed more tests and drugs than strictly necessary.

3.10. Regulatory Climate and Private Sector Engagement

3.10.1. Notification of TB

The majority of the PPs in the urban area were aware that TB was a notifiable disease through a letter from the DTO asking them to notify the number of TB cases diagnosed or treated by them. PPs stated that currently they were not reporting any information to the government about the number of cases treated by them. However, they expressed their willingness to notify, if a systematic process was developed to report the required information. They acknowledged that many cases treated by them were not accountable to anybody, since they did not enter into the government statistics. The majority of providers were willing to maintain a register to record the statistics of the TB patients treated by them. There was also concern that the RNTCP would snatch the patients from them or that the confidentiality of the patients' information would be lost.

#	Item	Amount (Range in INR/month)	Cost for 6 months of TB care in INR
1	PP's Consultation fee	30 - 200	180 - 1200
2	Kickbacks (30% of Laboratory and Drug costs i.e. #4 & 5 respectively)	75 - 1200	450 - 7200
3	Total Earnings of PP from a TB Patient (1+2)	105 - 1400	630 - 8400
4	Laboratory (one-time cost)	100-1000	100 - 1000
5	Pharmacy	150 – 3,000 per month	900 – 18,000
6	Total Cost to a TB Patient (1 + 4 + 5)	280 - 4,200 (~ USD 5-70)	1180 – 20,200 (~ USD 20-337)

Among the private diagnostic laboratories and pharmacies, awareness about notification was far from widespread. 22% of the pharmacists interviewed had the knowledge that TB notification is now mandatory as per the government policy. Among laboratory technicians there was virtually no knowledge of TB notification since they had no mechanism of obtaining reliable information from the government. Across regions, the process of notification was confused with referrals made to government health facilities for diagnosing TB. Several laboratories reported referring the suspected TB patients to government laboratories as evidence of their compliance with the notification policy. PPs who referred cases regularly to the RNTCP also tended to sometimes treat patients on private treatment. When asked whether they were notifying the cases, they replied saying that there was no need to notify, as their cases were usually referred to the RNTCP. Even in cases where technicians and pharmacists were aware of the requirement to notify TB patients, there was no clarity on the exact mechanism and procedures involved. This was also true among PPs, a majority of whom agreed to notify if the government provided a simple format and had a reporting system. It was observed that information typically percolated down through informal sources that were not uniformly reliable. For example, one technician said that he received information about notification from his friends working in government hospitals, *"I know many lab technicians in the government hospitals. They are my friends. They inform me about it."* Professional associations for laboratory technicians were either non-existent or non-functional. Respondents provided several recommendations for the effective implementation of notification, such as utilizing Anganwadi and/or field health workers to spread awareness or to advertise to improve the awareness of the process of notification for TB. The need for the public health system to take greater responsibility for enabling notification was repeatedly emphasized: *"what I feel is from your side you need to keep a representative and ask them to meet the set of practitioners who have identified and inform them to collect the data. You have to convince them at least to maintain the data."*

"There is a lot of staff in the government. They can come here monthly once or twice and collect the data from us. If they come and follow up then we will at least update the cases. If there is nobody to ask us then we will not update the data. They have to do it regularly".

One suggestion was to have a toll free number provided by the DTO which PPs could either call or SMS about notification. This number could be integrated for the purpose of all notifications, including polio, dengue, and TB. *"If you give one toll free number, atleast from morning to evening we might get some 100 cases. We will notify atleast 6 cases out of 10 cases."* In addition, it was also suggested to earmark one day from the government machinery to collect such information from private institutions to prevent conflicts with the regular functioning of these institutions. It was also emphasized that there should be one single system to report rather than having too

many options of Internet, phone, postal, or runners that may lead to confusion. Inadequate enforcement of notification policies by the government was also pointed out by the PPs: *“Notification is a must that has to be strictly implemented. Forcing a doctor to send the patient to RNTCP is not possible. Notifying it has to be made strict. Involvement of private practitioners has to be made compulsory for all these things. It has to be regularized”*. Currently, there are neither incentives nor repercussions to encourage PPs to notify. *“Private practitioners will not do it on their own interest. The government has to provide simple format. Then it will be filled up by the doctor's assistants”*. One PP while agreeing to notify, emphasized the need for the government to provide feedback *“If we maintain the record and feedback is not available, what is the use?”*

3.10.2. NIKSHAY

PPs reported that the primary issue with regard to using NIKSHAY was the lack of Internet connectivity. A rural GP, who treated around 15 TB suspects a month, said that it was not practical to introduce electronic reporting in the rural area: *“We don't know about the Internet. We don't know how to use. If mobile number provided, information can be given. That is easy. Writing in post is also not possible for notification”*. Even where there was Internet access, PPs may not be tech-savvy and hence could be expected to adopt this new technology without training and encouragement.

3.10.3. Ban on serological tests for TB diagnosis

Awareness about the ban on serological tests for TB diagnosis was almost completely absent among private laboratory technicians. However, the usage of serology tests to diagnose TB was found to be still relatively uncommon among the surveyed private facilities with only the larger, more affluent laboratories offering these tests. Serological tests were almost never performed for TB diagnosis and were relatively rare even for other conditions. Where available, the kits were procured from the urban area and the cost of these kits seemed to be a factor in the absence of widespread use of these tests. The researchers found that awareness and use of Interferon was next to nil with not even a single laboratory performing the test for TB diagnosis.

Chapter 4

Recommendations

This study demonstrated the complete absence of formal engagement of PPs with the RNTCP, 12 years after the launch of the PPM schemes. However, 22.4% of the PPs in the study area had made at least one referral to RNTCP during the study period, contributing to 23.2% of detected sputum smear positive TB cases. Also, data from TB patients' interviews suggested that 20 out of 28 PPs had referred patients to RNTCP. This showed that PPs were participating in the program, but on an ad hoc basis. A high positivity rate of 23%, which is much higher than the normally expected value of 10% among the patients referred by PPs, suggested that they were making selective referrals. PPs referred a substantial number of TB suspects, even though there were no formal financial payments made to them. These data strongly indicate that systematic efforts by the government to promote the engagement of PPs in RNTCP will yield dividends. Many reasons emerged from discussions with PPs and RNTCP government officials. The lack of flexibility and capacity of the government machinery to interface with a diverse and pluralistic private health sector was flagged as the biggest factor in the poor success of PPM schemes. The following paragraphs discuss the various challenges for collaboration between the government and private health sector.

4.1. Incentives

Result-based financial incentivization has been the operational model of the current PPM schemes. PPs who reported that financial incentives were necessary for collaboration suggested that the amount of financial incentive should be attractive enough for PPs and that the amount should be disbursed to PPs without too many bureaucratic hurdles to negate the delay. Direct cash transfer to reduce middlemen was one suggestion made by them. A few countries have tried mobile technology for disbursing the money, which could be piloted in India to test and understand the efficacy of using such technologies. However, many PPs opined that non-financial incentives should be provided to PPs to encourage them to collaborate. Some felt that the notification order should be used to enforce notification of TB cases, while others felt that it would be better to appeal to the social motive and encourage PPs to voluntarily get involved in RNTCP and notify TB cases. There may be some merit to the argument since the current engagement of the private sector with government schemes were not really driven by financial incentives. An interesting recommendation to decentralize the incentivization process and arrive at locally appropriate approaches was made. Suggestions were made to create a district TB alliance under the RNTCP, wherein the program designated a private sector player in a district as the chief coordinator of PPM and provided him/her with the required financial incentives to engage with other PPs in the area. It could be a reputed hospital

or a nursing home, but not an individual practitioner. The specific establishment could in turn be motivated to empanel as many doctors or nursing homes as possible. The logistical feasibility of such approaches needs to be considered but one of the learnings from successful partnerships, such as in the case of medical colleges, has been to give more ownership to the participant.

This study clearly demonstrated the existence of kickbacks to PPs while treating TB patients and PPs have financial incentives to retain patients. In fact, PPs were able to earn more from the kickbacks obtained from diagnostic laboratories and pharmaceutical companies than from consultation fees. This is thus an important factor that any PPM scheme to engage PPs into the RNTCP program must overcome. Meager financial incentives will not be adequate to encourage greater participation in PPM schemes since private sector health practitioners have multiple avenues to earn money. Financial incentives would have to be more lucrative than those available to PPs by retaining TB patients. The government however can incentivize PPs in other ways that may be more meaningful such as some kind of favored status, accreditation or certification that would raise the profile of PPs or improve their visibility within their local communities.

4.2. Change in PPM Guidelines, Thinking and Logic

As mentioned earlier, TB patients seek care from the private healthcare providers. Hence every effort to control TB should also prioritize the ways to engage with PPs optimally. As found in other studies, patients prefer to seek care from PPs because of various reasons. Behavior of the private provider is very different from a provider in a government facility. For instance, waiting time is shorter, approachability, perceived quality, etc. are different in the private sector. However, they receive sub-optimal diagnosis and treatment there. The private sector is larger than the public sector and has more patients. The dynamics there is different. With the available resources in RNTCP, it will be difficult to engage with the large and unorganized private sector in India. The program does not have any control over the current happenings in the private sector. The RNTCP alone cannot handle this, since it has no such mandate. Hence, the RNTCP has to re-examine the ways of collaborating with PPs. As a PP says, the government should make strategies to involve different PPs in terms of infrastructure, manpower, locality, and engage them in different ways: “ *If the government does not use the private practitioners then it is a loss for the government and the people. They need to utilize our services. There should be a separate wing for the private sector*”. This view was also echoed by a technocrat and an administrator, who stressed on the need to consider differences in the functioning of the private and public health sectors. They recommended setting up of an interface agency, which can have a district level nodal person to act as an interface between public and private sector to resolve the concerns from both ends.

Most PPs considered detect and refer arrangements as the best possible means of collaboration between PPs and government. Though many PPs agreed to be part of

the RNTCP, it was mainly with regard to the referrals of TB suspects. They reported that it was difficult to provide DOTS or to do default retrieval. Unfortunately, the current PPM guidelines fail to address this core activity of referrals from PPs. Currently there are no schemes available for referrals and hence the need to revisit the existing PPM schemes. Instead of the old traditional system of training through lectures, the use of technology through videos or small messages using mobile or smart phone applications to have more impact was emphasized. It was observed that those PPs who referred patients to the RNTCP were convinced about the RNTCP only through the trainings that they had received. Contrastingly, it was observed that none of the non-involved providers had received any kind of training in RNTCP. Informal providers tended to have poor knowledge but needed to be engaged with and trained since they treat a substantial number of patients. Involving them for referrals might be the best option. In addition to PPs, private pharmacists also need to be engaged in such trainings as well since they sometimes double-up as primary caregivers, especially in poorer communities. Continuous engagement of PPs through the umbrella of medical associations for CME sessions and dissemination of NTP guidelines was emphasized.

4.3. PPM Reporting System

The study area did not have any registry of PPs. Hence, the researchers had to use various data sources to map PPs. This process was time-consuming and resource-intensive. A good situational analysis of the private sector landscape including systematic mapping of all healthcare providers is a prerequisite for an effective PPM strategy, especially so in India, which has a pluralistic private health sector. Therefore clear guidelines should be developed by the government to facilitate program managers to carry out the mapping of PSPs. There are several tools to conduct private sector mapping that could be adapted and used by the RNTCP. It was observed that laboratory technicians at DMCs did not routinely document the source of referrals. WHO recommends that the source of referral and the place of treatment should be routinely recorded and reported to assess PSP's participation in the national TB program. This practice will prove useful in prioritizing the efforts of engaging PPs who are most likely to contribute to RNTCP.

There have been many efforts by the government to engage with PPs, however little or no effort has gone towards strengthening the PPM reporting system. RNTCP claims to have a robust reporting mechanism in place. But this data generated (either case detection or treatment outcomes) is only about patients notified by public sector health facilities and does not include contributions made from PPs. PPs' contribution to the RNTCP is not routinely measured and reported in the program in India. PPM section of the RNTCP quarterly reports fail to capture any useful information on the contribution made from PPs to the RNTCP. It provides only the absolute number of PPs involved in any PPM scheme and does not provide any disaggregated data according to different types of healthcare providers, which could help program managers in planning. This could be the reason why India is unable to report the

contributions made by PPs to TB notification except those of PPs from 14 PPM intensified sites. Studies have shown that how in the absence of clear performance related indicators, RNTCP staff may circumvent PPM activities as it neither offers any incentives nor contributes to their measurable performance(53).Hence, this study calls for immediate efforts to amend and strengthen the PPM reporting system by developing simple tools to measure PSP contribution. For this purpose, RNTCP could use several recording and reporting tools already available and also learn from the experience of PPM surveillance system in 14 PPM intensified sites in India (49),(54).

4.4. Enforcement of Regulation

In 2012, a number of key decisions were taken by the government in an effort to enhance TB control. This included the banning of inaccurate serology-based tests to diagnose TB, making TB a notifiable disease, i.e., mandatory reporting of TB cases to the government, and the launch of NIKSHAY, a case-based, web-based recording, and reporting system for TB. While these are positive measures, their effectiveness will depend on the enforcement and implementation within the private health care system. Along with framing of some regulation to control private sector players, the role of the government should also change. It was suggested that, the government should oversee the program instead of doing day-to-day work. It should enforce notification and penalize the defaulters. Respondents recommended surveillance of the program. If there is information about a TB patient under private treatment, the government should make efforts to investigate who diagnosed and/or treated it, etc. PPs do not notify the cases treated by them for the fear of losing the patient. Suggestions were made that the program needs to have a mechanism where the patient has the choice to go to the PP for the consultation and follow ups, with the program only supervising the patient. PPs at the end of treatment can provide the information to the program whether the patient is cured. For this purpose, there is a need to formulate some guidelines along the lines of RNTCP, to enable the PP to do the follow up. A system should be built in to retrieve defaulting patients who are on private treatment. This process must be made simple, where a PP can make a phone call to the nodal person at the RNTCP unit to inform them about a defaulting patient.

Several suggestions were made with regard to how RNTCP needs to change to accommodate the private sector players. The first and foremost suggestion was that RNTCP needs to be more flexible if it wants to engage PPs in an effective way. The program should stop policing the PPs, but instead constantly interact with them to sensitize the providers about international standards for TB care. Private providers use different modalities for making TB diagnosis and as a clinician they are justified. However if any tests are banned, they need to respect the mandate. PPs should have some flexibility within the broader guidelines of RNTCP. However, PP should also assume more responsibility in ensuring that the patient completes the treatment. In cases where the PP is unable to do it the program should establish a mechanism to see to that the patient successfully completes treatment. Given this flexibility, it also

becomes PP's responsibility that, they notify such cases treated by them. If not, they should be penalized.

4.5. Health System Strengthening

Our study reiterates the finding in the Global TB report 2012 and other studies that in TB high burden countries, the percentage of TB incident cases covered by the private sector is unclear. We discovered that the details of PPs, who refer suspects, are not recorded in the laboratory registers of DMCs. Hence there is a clear need for strengthening of documentation of referrals by PPs to assess their participation in the RNTCP and to make further improvement in the collaboration. Generally, the monitoring of PPM activities by the government is poor. Decisions about how performance will be monitored, how performance will be reported, measured, and monitored, and who is responsible for each role, are all factors that need to be strengthened in the program. The monitoring and supervision mechanism within medical colleges to oversee the implementation of RNTCP could serve as a positive model for designing a system for monitoring and evaluation.

Respondents opined that after the implementation of RNTCP, the number of TB cases going to private facilities has reduced. The continued focus of the public health programs on TB has led to considerable capacity building among government facilities. Simultaneously it has led to increased confidence of the general public on these facilities and an increasing reliance on them, especially in rural areas where other alternatives are fewer and of variable quality. But the existence of PPs, pharmacies and laboratories that continue to cater to TB patients, particularly in urban pockets, points to the need to further improve the functioning of government facilities. Government hospitals are yet to become the first choice for patients at large, who continue to be at the mercy of an unreliable private sector operating in a competitive market. However, the data suggest that the public sector when run effectively can successfully outperform the private sector. In smaller areas, government facilities take up a big share of the market; whereas, in big cities the competition is mainly within the private sector, and the public sector is a relatively minor player that is unable to compete on equal terms. While the dynamics within the governmental system were not captured in the analysis, it is clear that the influence and consequently bargaining power of the PPs in a given area is inversely proportional to the strength of the public health system in that area.

A significant improvement in government facilities may also increase the standard of care from its private sector competitors who currently operate purely to maximize profits. Some concerns raised in this study such as, public health facilities being unreliable, rigid work timings, poor staffing, frequent transfers of officials, and no mechanism of redress, need to be addressed by the government as a priority. The government needs to become more responsive to the needs of the community and change its attitude towards the private sector. As one respondent put it, *“the government should not to treat the private sector as their enemy but as an asset”*.

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